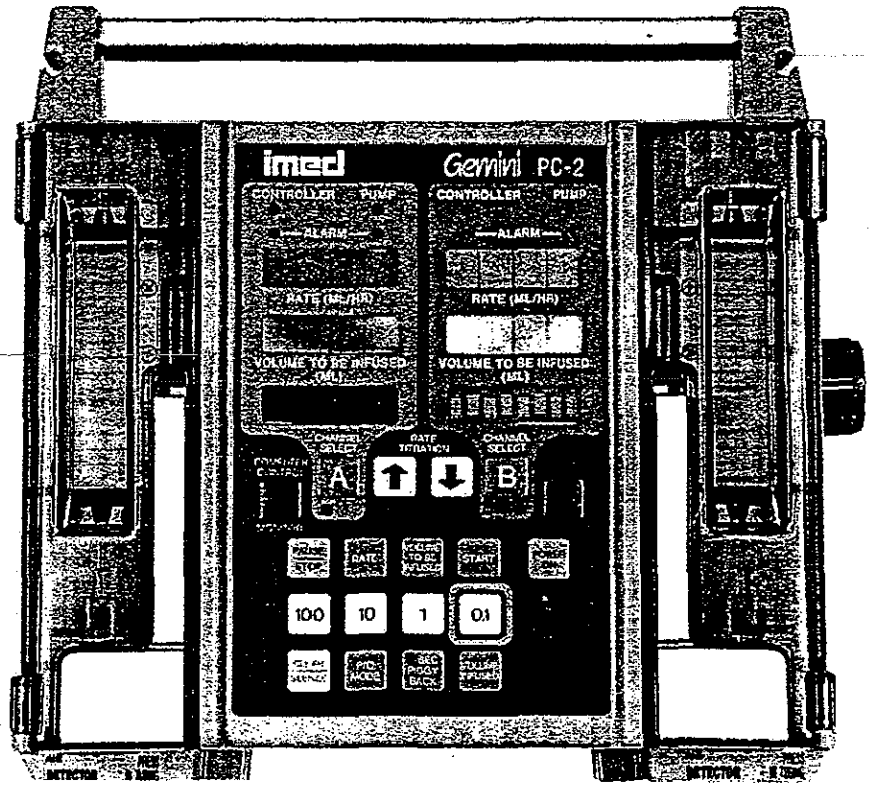
ALARIS™
MEDICAL SYSTEMS

110V and **220V**



imed® Gemini PC-2®

VOLUMETRIC INFUSION PUMP/CONTROLLER

MAINTENANCE MANUAL

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PREFACE

This manual contains operation and maintenance instructions for the series of IMED® GEMINI PC-2® Volumetric Infusion Pumps/Controllers ("PC-2"). The information provided herein is intended for use by technical personnel responsible for servicing these products. The material is divided into six sections and is presented as follows: Section 1 - Descriptive Information; Section 2 - Preparation for Use; Section 3 - Operating Instructions; Section 4 - Functional Description and Schematic Diagrams; Section 5 - Maintenance Instructions; Section 6 - Parts Lists and Assembly Drawings; Section 7 - Calibration and Preventative Maintenance.

Additional copies of this manual may be obtained by contacting your nearest ALARIS Medical Systems™ Customer Service Department.

This manual supersedes PC-2 Maintenance Manuals, P/N's 1320-9050-03,1320-9243-00, 141880, and PC2 International Addendum P/N 1320-9033-01.

The features of the 220V model of the PC-2 have been incorporated into this manual. Text or graphics that are related exclusively to the 220V model are identified with a 220V symbol.

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WARRANTY

SALES AND SERVICE OFFICES

TECHNICAL SERVICE MANUAL SUPPLEMENTS

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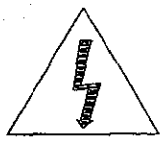
WARNINGS, CAUTIONS AND NOTICES

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

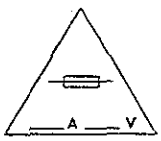
Use only hospital grade power supply cord to insure proper grounding. Grounding reliability can only be achieved by connection to a receptacle marked "HOSPITAL GRADE".

DANGER: EXPLOSION HAZARD, DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS.

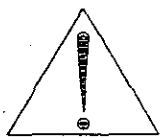
WARNING: TO PREVENT UNRESTRICTED FLOW, CLOSE CLAMP WHEN FLO-STOP IS OPEN.



CAUTION: TO REDUCE RISK OF ELECTRICAL SHOCK, DO NOT REMOVE COVER OR BACK. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.



WARNING: REPLACE FUSE AS MARKED.



CAUTION: BEFORE CONNECTING "REFER TO MANUAL"

NOTE

TO MAXIMIZE THE SERVICE LIFE OF THE INSTALLED BATTERY, IT IS RECOMMENDED THAT THIS INSTRUMENT BE STORED AND OPERATED IN AN ENVIRONMENT THAT IS TEMPERATURE CONTROLLED BETWEEN 68°F (20°C) AND 77°F (25°C).

WARNING

IN THE EVENT THE INSTRUMENT IS DROPPED AT ANY TIME, IT MUST BE CHECKED BY A BIOMEDICAL TECHNICIAN PRIOR TO USE FOR PATIENT CARE.

WARNINGS, CAUTIONS AND NOTICES 220V

WARNING: TO PREVENT UNRESTRICTED FLOW, CLOSE ROLLER CLAMP WHEN FLO-STOP® IS OPEN.

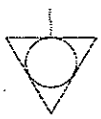
CAUTION: REFER TO MANUAL

CLASS 1

TYPE CF (Equipment useable for direct cardiac applications)

ALTERNATING CURRENT

REPLACE FUSE ONLY WITH SAME TYPE AND RATING



EQUIPOTENTIAL GROUND POINT: IF THE INTEGRITY OF THE EQUIPOTENTIAL EARTH CONNECTION OR HOSPITAL EARTH SYSTEM IS IN QUESTION, OPERATE THE INSTRUMENT USING INTERNAL BATTERY POWER.

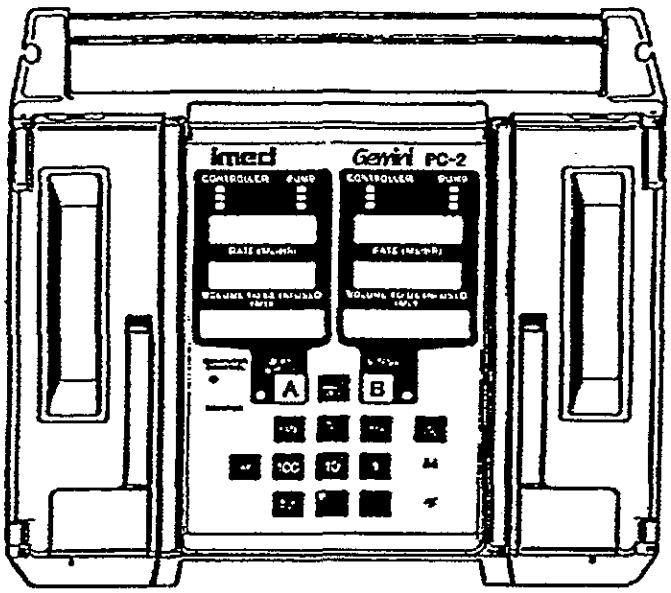
IPX1 **DRIP PROOF**

CAUTION

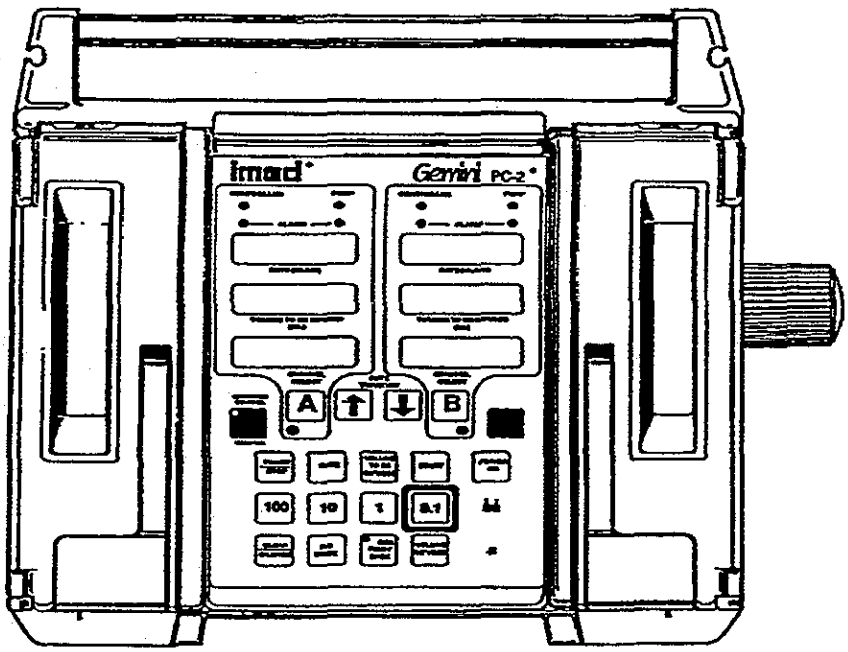
ONLY equipment that has been qualified to IEC 601-1 standards should be connected to the PC-2's RS-232-C Data Port and the connection should ONLY be performed by qualified personnel.

CAUTION

Only systems that have been qualified to IEC 601-1 standards should be connected to the PC-2's Nurse Call connector and the connection should ONLY be performed by qualified personnel.



Integer keypad



Fractional/Titration Keypad

Figure 1-1. IMED® GEMINI PC-2® Volumetric Infusion Pump/Controller

SECTION 1 - DESCRIPTION

1.1 INTRODUCTION

This section includes general operating characteristics, physical description and operating specifications for all versions of the IMED® GEMINI PC-2® Volumetric Infusion Pump/Controller ("PC-2").

1.2 OPERATING CHARACTERISTICS

The GEMINI Model PC-2 is a dual channel volumetric infusion pump/controller used in the administration of intravascular drugs and fluids. Each channel is capable of independent operation in either the Pump or Controller delivery mode. The pumping mechanism employs linear peristaltic action. The peristaltic action is provided by a series of 12 cam-actuated fingers that sequentially collapse then release, in a ripple-like action, the soft pumping segment of a GEMINI administration set. This action produces a positive pressure at the outlet side and a vacuum on the inlet side of the pump, thereby delivering a continuous flow of infusion solutions reliably, accurately and with a high degree of safety.

The dual channel configuration enables a variety of infusion techniques including independent primary, simultaneous primary and sequential secondary. Independent and simultaneous primary infusions can deliver either a specified volume or the entire contents ("ALL") of a solution container. Use of the ALL setting requires installation and connection of an Empty Container Detector (ECD) which is available as an optional accessory. Sequential secondary (piggyback) infusions with independently defined delivery parameters, for both the primary and secondary solutions, can be provided on each channel.

Operational control of the PC-2 is affected through the control and indicator panel on the front of the case and the Audio Control switch on the rear panel. Basic operating instructions are printed on the right side of the instrument case. Functional control is provided by a 16 bit micro-processor with a stored program that includes a maintenance/diagnostic mode to monitor instrument performance, an audio/visual alarm subsystem to alert operators to abnormal conditions and redundancy checks to confirm system accuracy.

1.3 OPERATING CONDITIONS

The PC-2 can be operated independently (Normal Operation) or as a computer controlled device (Computer Operation). Normal operation includes the Controller and Pump modes plus a Maintenance mode. Computer operation includes Monitor and Computer Control modes.

NORMAL OPERATION

SETUP MODE

<u>Fractional Keypad/Series 3.xx Software only</u>
The Fractional/Titration keypad instrument utilizes the Setup Mode (refer to Figure 3-1a) to configure the instrument for specific infusion regimes, language selection and communication (serial port) parameters.

CONTROLLER MODE

In the CONTROLLER mode, the PC-2 is programmed to control the infusion of a specific volume of IV solution. The instrument senses and responds to patient-side pressure and container height in a manner similar to a gravity infusion. The instrument's pressure sensor measures the hydrostatic pressure from the bottle and compares that pressure against distal tubing in-line pressure. When in-line pressure exceeds pump input pressure, an occlusion condition exists and an alarm is initiated. Actual delivery pressure is directly proportional to container height; increasing container height raises and decreasing the height reduces occlusion pressure. Controller mode occlusion pressure tolerance is ±12 inches (30.5 cm) from the bottle height. Transient surges in patient-side pressure of <60 seconds duration will produce a LOW FLOW condition which stops the infusion while the pressure is above the occlusion threshold. Pressure transients above the occlusion

threshold >60 seconds duration or cumulative time required to compensate for volumetric deficiency caused by periods of Low Flow in excess of 30 minutes will cause an occlusion alarm.

PUMP MODE

In the PUMP mode of operation, the instrument employs a preset occlusion pressure limit of 10 ±2 psi (69 ±14 kPa) predicated on a nominal container height of 24 inches (61 cm) and a delivery rate >30 mL/hr. For delivery rates <30 mL/hr, the occlusion pressure is rate dependent to ensure timely detection of occlusion conditions. Any transient distal in-line pressure above this limit will generate a patient-side occlusion alarm.

Fractional Keypad/Series 3.xx Software
These instruments when operating in the Pump Mode can be locked into a reate-independent (10 psi) occlusion pressure mode. This mode will result in significantly increased time-to-occlusion for rates <30 mL/hr.

MAINTENANCE/DIAGNOSTIC MODE

Integer Keypad/Series 2.xx Software
The maintenance mode is intended solely for use by biomedical technicians to perform servicing and maintenance actions and **must never be used when the PC-2 is connected to a patient**. The maintenance mode provides biomedical service personnel access to the closed loop diagnostic test routines, allows the pumping mechanism to be operated uninterrupted by stoppages resulting from alarm conditions and maintains an error code log (see Section 5.3 for detailed operation).

Fractional Keypad/Series 3.xx Software
The diagnostic mode provides biomedical service personnel access to the closed loop diagnostic routines, allows the pumping mechanism to be operated uninterrupted by stoppages resulting from alarm conditions and maintains a log of the 10 most recent error codes (see Section 5.3 for detailed operation).

COMPUTER OPERATION

MONITOR MODE

The Monitor mode allows a host computer to monitor infusion status and instrument performance. Monitor mode is enabled when a host computer is connected to the PC-2 through the Communications Data Port and the Monitor indicator is illuminated.

COMPUTER CONTROL

The Computer Control mode allows an infusion, once set up, to be controlled and monitored by a host computer installation.

1.4 USER INTERFACE

Infusion parameters are programmed into the instrument using the appropriate keys on the Control and display Panel. Delivery Mode, Rate and volume-to-be-Infused are input are input separately for each channel. Rate and VTBI for secondary infusions (piggyback) are also programmable, independent of the primary infusion parameters, for each channel. Visual Prompt and Advisory messages with accompanying audio alerts are provided to assist operators in setting up the instrument for operation. Infusion completions, alarm conditions and software-detected malfunctions are signaled by both audio and visual alerts; hardware-detected malfunctions are signaled by an audio warning.

Integer Keypad/Series V2.xx Software
Instruments configured with the 15 key Integer keypad provide tamper resistance through the requirement to actuate an ACCESS CHANNEL control prior to selecting P/C MODE, RATE or VTBI to change an infusion parameter or actuating either START or PAUSE/STOP to initiate or terminate and infusion.

Fractional Keypad/Series V3.xx Software
Instruments configured with the 19 key Fractional keypad provide: rate titration, and tamper resistance via the panel lock feature. Tamper resistance is enabled within the SETUP mode and implemented using the Audio Control switch on the rear panel. The Fractional keypad instruments also require the SELECT CHANNEL control to be actuated prior to selecting or changing infusion parameters and/or starting or terminating an infusion.

The requirement to properly install the administration set's integral Flo-Stop® flow control device before the door will close and latch prevents "free flow," inhibits premature operation of the pump and prohibits use of an unauthorized set. Door Open and Air-in-Line sensors are programmed to stop pump operation if either condition occurs during an infusion. A battery and battery charging

system are incorporated into the PC-2 to provide backup power in the event of a failure of the primary power source and to permit instrument operation under ambulatory conditions.

The rear panel of the PC-2 is configured with an ECD connection for each channel, a connector to accept a Nurse Call line (**which also accommodates the maintenance plug for maintenance mode initialization and operation for instruments with Software Release V2.13 installed**) and a standard RS-232-C communications data port for interfacing with a host computer.

IMED® GEMINI Series disposable administration sets are required for use with the GEMINI family of Infusion Pump/Controllers.

1.5 PHYSICAL DESCRIPTION

The PC-2 instrument has the following physical characteristics:

Height:	10.8 inches (27.4 cm)
Width:	11.8 inches (30.0 cm) with pole clamp
Depth:	7.3 inches (18.5 cm) with pole clamp
Weight:	≈17.3 pounds (7.8 kg) including power cord

The PC-2 instrument consists of two major assemblies: the front and rear cases.

FRONT CASE

The front case consists of a metalized, high-impact, injection molded, plastic case/insert which houses and supports the pumping chamber access doors, the peristaltic pumping mechanisms, pressure transducers (strain beams), Air-in-line, Slide clamp detectors, the multi-card assembly, keypad and front case ESD components.

REAR CASE

The rear case assembly consists of a die-cast aluminum shell which mounts and supports internally the battery, transformer, audio alert harness, power transistor harness and communication harness/circuit card assembly. The exterior of the rear case supports the pole clamp, ECD storage, power entry module, power cord retention strap and power cord retainer.

220V **only**. The exterior of the rear case supports the 220 VAC power entry module plus the equipotentiality grounding point. The power entry includes fuses for both input leads and a 220 VAC power interrupt switch.

1.6 PRODUCT HISTORY

The initial release of the GEMINI PC-2® Infusion Pump/Controller was in November 1987. Since that time a number of changes have occurred. Refer to Table 1-1 for product history.

1.7 OPERATING SPECIFICATIONS

The PC-2 Operating Specifications are subordinated into Operating Requirements and Performance Specifications which are delineated in Tables 1-2 and 1-3 respectively.

1.8 ACCESSORIES

The accessories approved for use with the PC-2 are listed in Table 1-4.

Table 1-1. Product History

Model	History
Integer PC-2	• Initial release of product Software version 2.xx.
Titration PC-2	• Titration Fractional rate, VersaTaper introduced Software version 2.52.
Titration/Fractional PC-2	• Rate Titration and Tamper Mode introduced. This unit has a Configuration Setup Mode that can be accessed by holding the "Setup" key at Power Up. The "Setup key is next to the "B" key Software Version 3.xx.

Revision Matrix:

Revision #	PC-2 2.xx	PC-2 2.52	PC-2 3.xx	PC-2 3.45
A	X	X	X	X
B				
C				
D		X	X	X
E				
F	X			

Revision "A" - Initial Revision
Revision "B" - Software Upgrade for International units to enhance operation.
Revision "C" - Software Upgrade to change "PSI" to "mm/hg".
Revision "D" - Mandatory Upgrade to incorporate "Crowbar" circuit for 2.xx units. This circuit will cause the line fuse to blow if the battery is in an overcharge condition.
Revision "E" - Not used.
Revision "F" - Mandatory Upgrade to incorporate "Crowbar" circuit for 3.xx units. This circuit will cause the line fuse to blow if the battery is in an overcharge condition.

Note[1]: xx = a number associated with a particular software version, i.e., 2.xx could be 2.09 or 2.13 or 2.16 etc.

Note[2]: All PC-2s have a Maintenance or Diagnostic Mode. To access this mode: hold in the Computer key at Power Up; press the "Computer" button to step through; press the "Start" button to access each function.

CAUTION: The "Fractional" and "Integer" Pumping Mechanisms are not interchangeable.

Table 1-2. Operating Requirements

Parameter	Specification
Power Required:	**Non-Dual State Charger Instruments** 90-132 VAC, current draw 0.30 Amps nominal, 36 Watts, fused at 0.4A, 50-60 Hz, 3 wire, Single ϕ **Dual State Charger Instruments** 90-132 VAC, current draw 0.45 Amps nominal, 54 Watts, fused at 0.6A, 50-60 Hz, 3 wire, Single ϕ
220V	**Integer Keypad Instruments WITHOUT Dual State Charger** 220-240 VAC, 0.15 Amps nominal, Fused at 0.315A, 50-60 Hz, 3 wire, Single ϕ
220V	**Integer and Fractional Keypad Instruments with Dual State Charger** 220-240 VAC, 0.25 Amps nominal, Fused at 0.400A
Battery:	Sealed lead-acid, 6 VDC, 12 Amp-Hr
Nurse Call System Power Limitations:	Maximum recommended Voltage/Current 24 VDC/500 mA
Operating Temperature Range:	40°F (5°C) to 104°F (40°C)
Operating Humidity Range:	0% to 95% Relative Humidity, non-condensing
Storage Temperature:	-40°F (-40°C) to 158°F (70° C)
Storage Humidity:	40% to 95% Relative Humidity, non-condensing

Table 1-3. Performance Specifications

Parameter	Specification
Operating Principle:	Linear Peristaltic
Operating Range: Pump and Controller modes:	
Integer Keypad/Series 2.xx Software	
Rate:	1 - 999 mL/hr in 0.1 mL/hr increments **(Controller mode maximum recommended rate is 500 mL/hr)**
Volume-to-be-Infused (VTBI):	1 - 9999 mL in 1 mL increments mL/hr
Keep Vein Open (KVO) rate:	1 mL/hr
Fractional Keypad/Series 3.xx Software	
Rate:	MICRO: 0.1 - 99.9 mL/hr in 0.1 mL/hr increments **(Controller mode maximum recommended rate is 500 mL/hr)** MACRO: 1 - 999 mL/hr in 1 mL/hr increments UNIVERSAL: 0.1 - 99.9 mL/hr in 0.1 mL/hr increments; 100 - 999 mL/hr in 1 mL/hr increments

Volume-to-be-Infused (VTBI):	MICRO: 0.1 - 999.9 mL/hr in 0.1 mL/hr increments MACRO: 1 - 9999 mL/hr in 1 mL/hr increments UNIVERSAL: 0.1 - 999.9 mL/hr in 0.1 mL/hr increments; 1000 - 9999 mL/hr in 1 mL/hr increments
Keep Vein Open (KVO) rate:	1 mL/hr for delivery rates ≥1 mL/hr, or set delivery rate if <1.0 mL/hr
Occlusion Pressure -	
Controller Mode:	±12 inches (±30.5 cm) from nominal bottle height
Pump Mode:	10 ±2 psi (69±14 kPa) (at delivery Rates below 30 mL/hr occlusion pressure is flow rate dependent to ensure rapid response to occlusion conditions) **Fractional Keypad/Series 3.xx Software** 10 psi mode - occlusion pressure is set at 10 ±2 psi for all rates.
Air-In-Line Detection:	Ultrasonic (nominal 75μL embolus)
Secondary (Piggyback):	Dual rate programmable
Nurse Call Feature:	Activates an externally powered system in the event of an Alarm, Malfunction or selected Advisories
Communications Data Port:	EIA Standard RS-232-C. Requires standard 9 pin subminiature D connector
Visual Messages - 220V	**Software Release v2.xx** (Language selectable on the "a" version EPROM to English, German, Spanish and French. The "b" version EPROM provides English, German, Italian and Swedish).
220V	**Software Release v3.xx** All language selections available on installed EPROM.
ADVISORIES:	PRIMARY, SECONDARY, MAINTENANCE, PAUSE, INFUSION COMPLETE-KVO, LOW FLOW, EMPTY CONTAINER-KVO, LOW BATTERY, TOTAL VOL INFUSED and SEC VOL INFUSED **Fractional Keypads/Series 3.xx Software** MICRO, MACRO, 10 psi, SETUP, PANEL LOCKED and DIAGNOSTIC
ALARMS:	CHECK ECD, CHECK IV SET, CLOSE DOOR, AIR IN LINE, OCCLUDED, FLO STOP OPEN / CLOSE DOOR, OCCLUDED-PATIENT SIDE, OCCLUDED-FLUID SIDE, PARTIAL OCCLUSION-FLUID SIDE, COMM CABLE-KVO, COMM TOUT-KVO and KVO
MALFUNCTIONS:	HELP BATTERY, HELP INTERNAL ERROR and HELP RATE ACCURACY

PROMPTS:	SELECT P/C MODE, PRESS START, SET RATE, SET VTBI and **Integer Keypad/Series 2.xx Software** ACCESS CHANNEL **Fractional Keypad/Series v3.xx Software** SELECT CHANNEL
Relative Rate Indicator: **(v2.xx only)**	1-20 mL/hr: Minimum 1 sec/increment >20 mL/hr: Flash rate increases with infusion rate
Operating Indicator: **(v3.xx only)**	>500 msec all rates
Battery Operation:	With a new, fully charged battery, approximately 5 hours with one channel operating at 125 mL/hr, or approximately 4 hours with two channels operating at 125 mL/hr before "HELP BATTERY"

Battery Charging:

Instruments without Dual State Chargers

Instrument Off	4 hours will recharge a fresh battery to battery operation specification level (≈90% capacity)
Operating @ 125	18 hours recharge will restore a fresh battery to a fully charged condition

NOTE

To maximize battery life, recharge battery for 10 hours with the power off or 24 hours with the power on between consecutive battery operations.

Instruments without Dual State Chargers

Instrument off/Operating @ 125 mL/hr	4 hours will recharge a fresh battery to battery operation specification level (≈90% capacity) 10 hours recharge will restore a fresh battery to a fully charged condition

NOTE

Failure to fully recharge the battery between consecutive battery operations will reduce battery life.

Audio Characteristics:

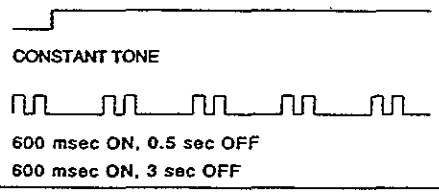
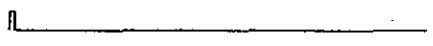
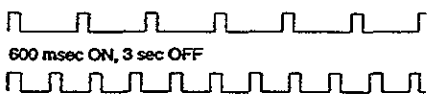
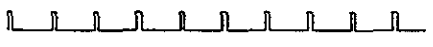
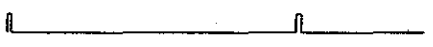
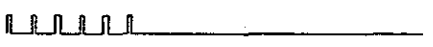
AUDIO TYPE	AUDIO PERIOD	VOLUME VAR/FIXED	SILENCE YES/NO
(1) MALFUNCTION v2.xx v3.xx		MAXIMUM 75db FIXED	NO
(2) KEY CLICK		VARIABLE	YES
(3) ALARM v2.xx v3.xx		VARIABLE	YES
(4) PROMPT		VARIABLE	YES
(5) ADVISORY		VARIABLE	YES
(6) CHANGEOVER		VARIABLE	NO (v2.xx) YES (v3.xx)

Figure 1-2. Audio Characteristics

Table 1-4. Accessories

Part No.	Description
1303	Communications Emulator Plug (optional)
1308	Universal Empty Container Detector [ECD]. Only compatible with Fractional/Titration Keypad Instruments and Integer Keypad instruments with the Communications Harness Modification Kit P/N 20-9205-7 installed.
20-1107-1	Maintenance Plug [use with V2.13 Software only] (optional)
2285	Syringe Holder
3299-100	Calibrated Tubing (optional)

SECTION 2 - PREPARATION FOR USE

2.1 INTRODUCTION

This procedure contains information relative to the initial inspection and pre-operational checkout of the IMED® GEMINI PC-2® Volumetric Infusion Pump/Controller ("PC-2"). These procedures include a mechanical inspection, electrical inspection, pre-operational battery charge and a performance check to ensure that the instrument operates properly and has not been damaged during shipment or storage.

2.2 PRE-OPERATIONAL MECHANICAL INSPECTION

The PC-2 has undergone thorough production control and quality assurance testing prior to shipment from the factory. The shipping container has been designed to protect the instrument against damage under normal shipping conditions; nevertheless, internal physical and/or electronic component damage could have occurred without leaving a visible signature. Therefore, it is recommended that the following inspection procedure be performed upon receipt of the instrument at the user's facility.

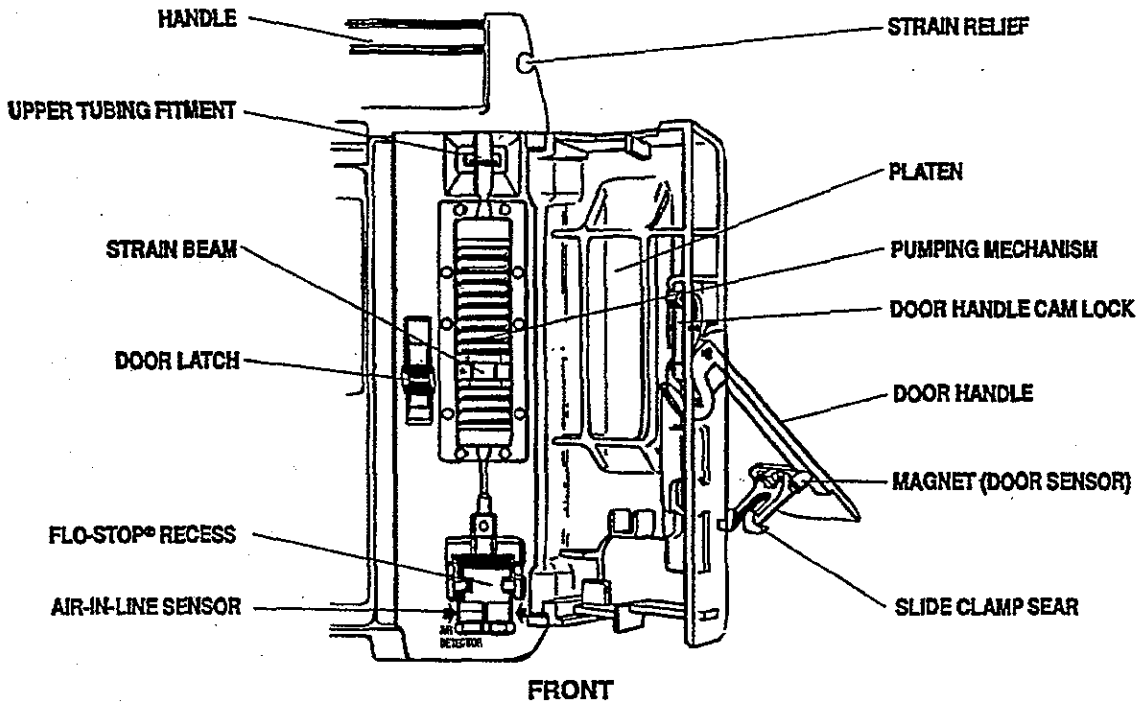
1. Carefully remove the PC-2 from the shipping container. (Save the shipping material for reuse in the event the instrument must be returned to the factory for service or repair).
2. Inspect the exterior case, front and rear, for holes, cracks, scratches, spalling, broken or damaged controls, missing components and/or screws.
3. Inspect the amber and green tinted windows covering the indicator displays for scratches or cracks.
4. Ensure the pumping chamber access doors fit flush with the case at the top, bottom, and sides.
5. Check the door handle/cam locks for ease of operation and flush fit with door when latched.
6. Inspect the pumping mechanism seals for damage and to ensure they are properly attached to the front case.
7. Inspect the Air-in-line sensors and Flo-Stop® recesses for damage or obstructions.
8. Install an approved IMED GEMINI administration set to ensure the Flo-Stop assembly seats correctly and the door closes and latches properly.
9. Inspect the power cord for damage, bent prongs or deformed connector.
10. Exercise the pole clamp mechanism to ensure freedom of movement.
11. 220V **Only (Figure 2-1a)** Inspect the AC Power Input Module for proper number and type of fuses, unrestricted operation of the Power Interrupt switch (where applicable) and for physical damage and/or missing parts.
12. 220V **Only (Figure 2-1a)** Inspect Equipotential Ground Point for damage and security.

NOTE

In the event the PC-2 shows evidence of shipping damage, notify the carrier's agent immediately. Do not return a damaged instrument to the factory before the carrier's agent has authorized repairs. Contact ALARIS Medical for authorization to return the instrument for repair regardless of liability for repair costs.

2.3 OPERATIONAL PERFORMANCE CHECK

Prior to the first operational use and following any routine maintenance or servicing of the PC-2, it is strongly recommended that an operational



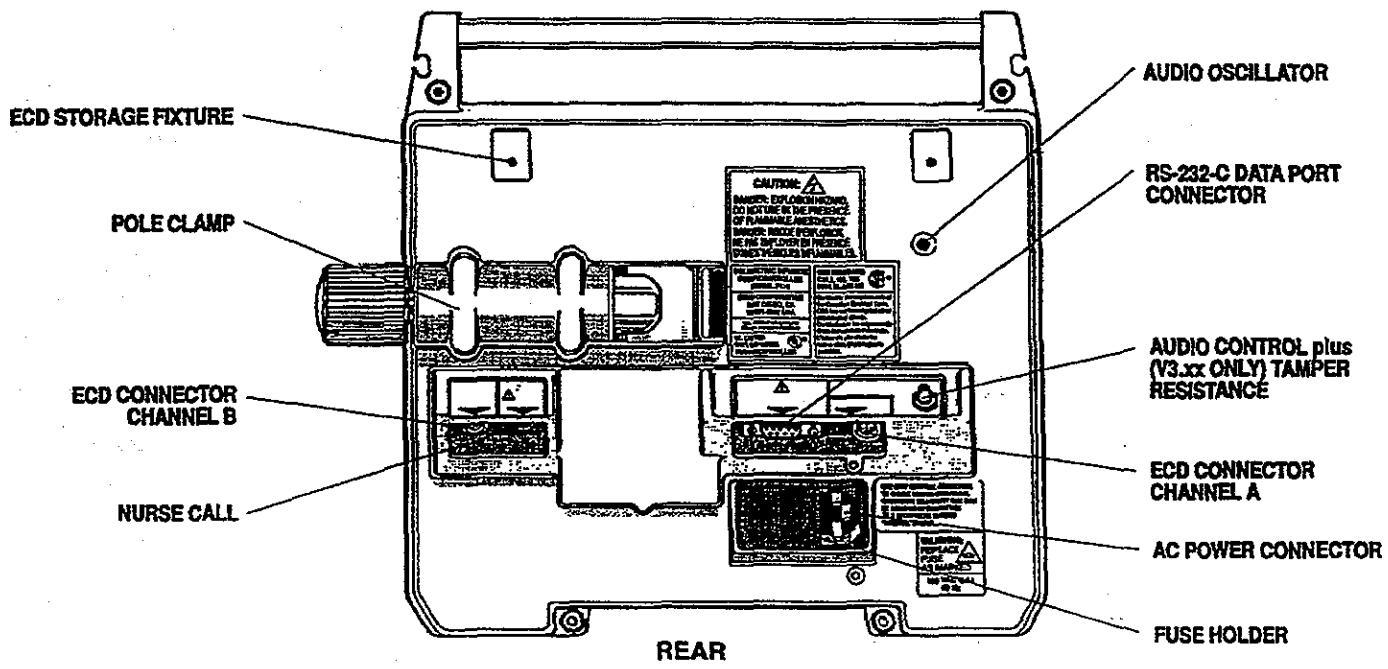


Figure 2-1. PC-2 Front and Rear Panel Operating Features

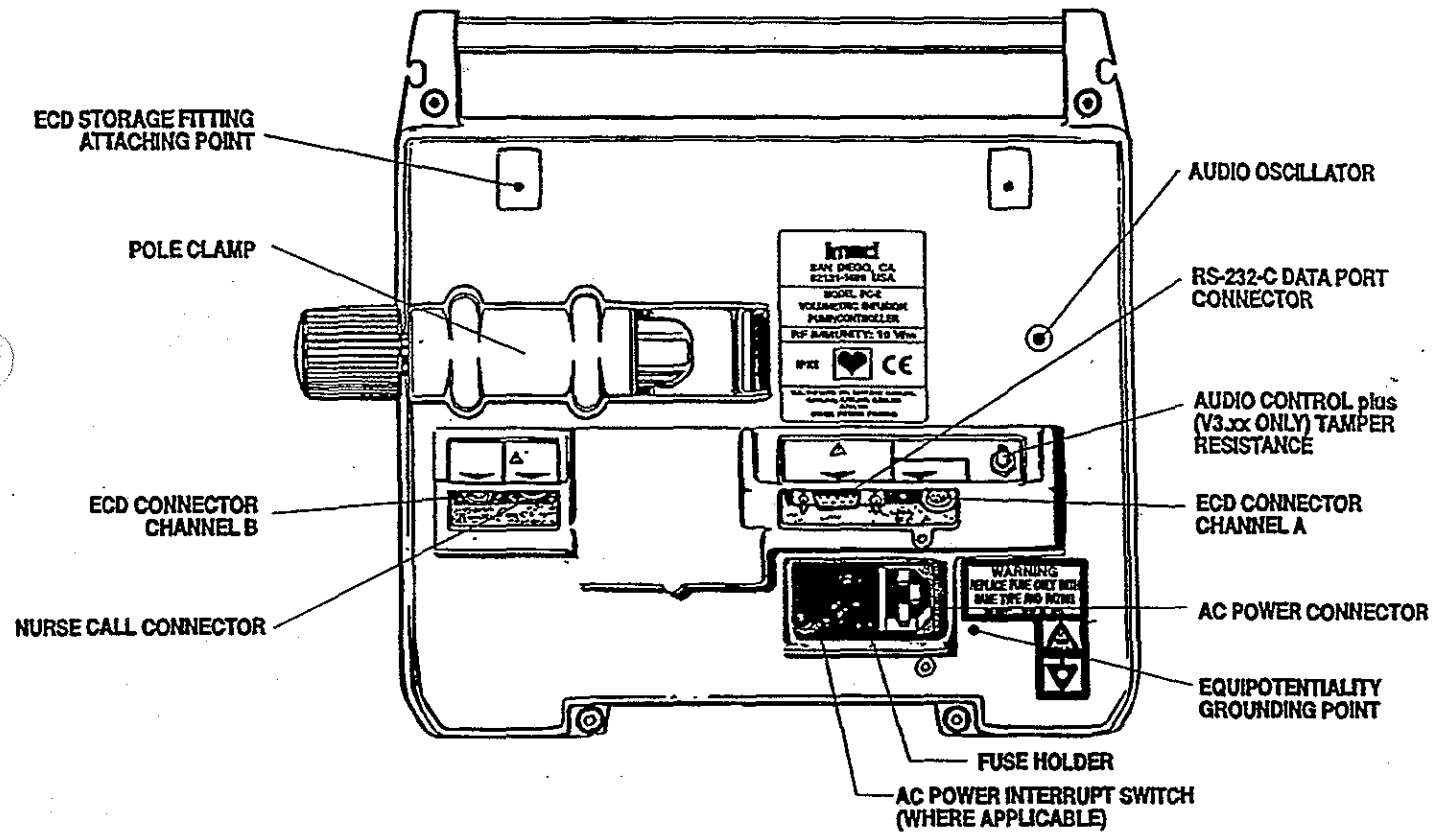


Figure 2-1a. PC-2 (220V) Rear Panel Operating Features

performance check be performed. The operational performance check consists of two phases; a Pre-operational Electrical Inspection to check the electrical integrity of the instrument for compliance with regulatory agency requirements and an operational performance test to verify pump/controller performance.

2.3.1 Pre-operational Check Battery Charge

The battery is in a fully charged condition upon completion of the post manufacturing quality assurance inspection. However, since considerable time could elapse between manufacture and first use, a pre-operational battery charge is recommended. Connect the AC power cord to a suitable AC outlet, 220V assure mains switch is on (where applicable), and allow the battery to charge for 24 hours.

2.3.2 Pre-operational Electrical Inspection

The pre-operational electrical inspection includes an electrical leakage test and a ground continuity check.

CAUTION

Some of these tests are inherently hazardous. Safeguards for personnel and property should be employed when conducting such tests. Tests should only be performed by qualified personnel.

2.3.2.1 Electrical Leakage Test

Perform an electrical leakage current measurement in compliance with Underwriters Laboratories (UL) 544 for Patient Care Equipment and/or Canadian Standards Association (CSA) Standard C22.2 No. 125 for Risk Class 2G Equipment. Leakage currents are to be less than 100 microamperes.

220V **only.** Perform an electrical leakage current measurement in compliance with IEC 601-1. Leakage currents are to be less than 100 microamperes.

2.3.2.2 Electrical Ground Test

Perform an electrical ground impedance measurement in compliance with UL 544 for Patient Care Equipment and/or CSA Standard C22.2 No. 125 for Risk Class 2G Equipment. The impedance between the grounding pin on the power cord plug and the grounding point on the rear case should not exceed 100 milliohms.

220V **only.** Perform an electrical ground impedance measurement in compliance with IEC 601-1. The impedance between the grounding pin on the power cord plug and the grounding point on the rear case should not exceed 100 milliohms.

2.3.3 Abbreviated Operational Performance Test

The following operational performance test is designed to ensure each of the PC-2's controls and indicators is functioning properly and check the operability of all the features available in the normal operating modes.

2.3.3.1 Test Requirements

The following items of laboratory equipment and supplies are required to conduct the operational performance tests:

1. Two (2) IMED GEMINI administrative sets with an upper injection site.
2. Two (2) IV Solution Containers.
3. Standard IV Pole.
4. Nurse Call Test Light (see figure 2-2).

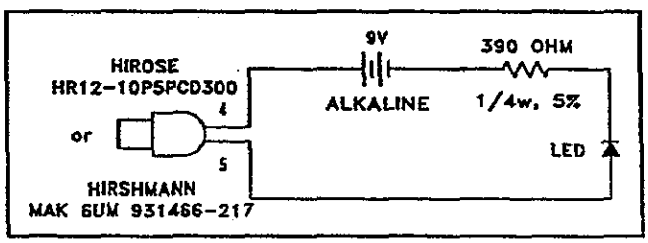


Figure 2-2. Nurse Call Test Light

5. Communications Emulator plug (see figure 2-3).
6. Hemostats.
7. Empty fluid container.
8. Gas tight syringe: 100 microliter capacity.

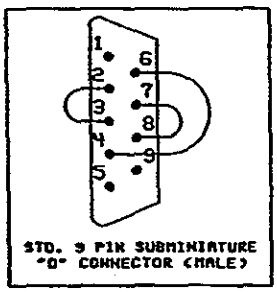


Figure 2-3. Communications Emulator Plug

9. Pressure gauge, 0-60 psig.

2.3.3.2 Test Procedures

The following tests and associated procedures are presented in a sequence that provides an efficient, qualitative check of instrument operability.

INITIAL SETUP

PC-2 control key locations are shown in Figures 3-1 and 3-1a and functionally described in Table 3-1.

1. Mount pump on IV pole (leave AC power cord unplugged).

2. Fill IV fluid containers with water and hang on IV pole 24" above PC-2.

3. Spike and prime administration sets.

4. Install Nurse Call Test Light in the Nurse Call/Maintenance Plug connector.

5. If available, attach ECD sensor to the set drip chamber (do not connect to the pump's channel A ECD receptacle until instructed).

Integer Keypad/Series v2.xx Software

6. Press POWER ON Control and check:
   - Battery Operation Indicator - Illuminated,
   - RATE and VTBI Displays show "8.8.8.8" momentarily then extinguish (except channel B VTBI which shows "8.8.8.8"
   - All LED indicators and dot-matrix elements illuminate momentarily then extinguish, except the upper LED position in either the Pump or Controller Mode/Relative Rate indicators.
   - A single audio Prompt is sounded.
   - "PC-2 Vx.xx" message scrolls once across the Status/Alarm Display (x.xx = software version).

Fractional Keypad/Series v3.xx Software

7. Press and hold the SETUP control, then press POWER ON and check:
   - Battery Operation Indicator - Illuminated,
   - RATE and VTBI Displays show "8.8.8.8" momentarily then extinguish (except channel B VTBI which shows "8.8.8.8"
   - All LED indicators and dot-matrix elements illuminate momentarily then extinguish.
   - A single audio prompt is sounded.
   - "setup PC-2 vx.xx press setup control" scrolls continuously (x.xx = installed software version).
8. Check instrument configuration:
   a. Press SETUP control - "tamper-resistant mode" scrolls continuously
      - Press START - "enabled" or "disabled" displays statically.
      - Use the ⇧ or ⇩ controls to select "disabled" setting.
   b. Press SETUP control - "P/C mode" scrolls continuously
      - Press START - "locked" or "unlocked" displays statically on each Operator Information display.
      - Selected Delivery mode indicator illuminates for each channel.
      - Use the A or B CHANNEL SELECT controls to toggle the respective channel between PUMP and CONTROLLER mode.
      - Use the ⇧ or ⇩ controls to select "unlocked" setting.
   c. Press SETUP control - "10 psi mode" scrolls continuously
      - Press START - "enabled" or "disabled" displays statically.
      - Use the ⇧ or ⇩ controls to select "disabled" setting.
   d. Press SETUP control - "macro/micro mode" scrolls continuously
      - Press START - "macro", "micro" or "mic/mac" displays statically.
      - Use the ⇧ or ⇩ controls to select "mic/mac".
   e. Press SETUP control - "Primary switchover alert mode" scrolls continuously
      - Press START - "enabled" or "disabled" displays statically.
      - Use the ⇧ or ⇩ controls to select either "enabled".

f. Press SETUP control - "communications setup" scrolls continuously
   - Press START - "serial #" displays statically.
   - Use 1, 10, 100 and/or CLEAR/SILENCE controls to input serial number.
   - Press PAUSE/STOP - "baudrate" displays statically.
   - Use the ⇧ or ⇩ controls to select baudrate (110, 300, 600, 1200, 2400, 4800 or 9600).
   - Press PAUSE/STOP - "parity" displays statically.
   - Use the ⇧ or ⇩ controls to select parity option (O [odd], E [even] or OFF).
   - Press PAUSE/STOP - "stopbits" displays statically.
   - Use the ⇧ or ⇩ controls to select stop bit option (1 or 2).

g. Press SETUP control - "language selection" scrolls continuously
   - Press START - currently selected language displays statically.
   - Use the ⇧ or ⇩ controls to select language option (english, german, french, italian, swedish, spanish).

h. Press SETUP control twice "exit setup" scrolls continuously.

i. Press START to exit setup and enter infusion Setup and Operation mode.
   - Battery operation LED flashes.
   - Rate and VTBI displays show "- - - -".

CHARGING INDICATION

1. Connect AC Power cord to a 120 VAC power source (220V) Assure Mains Switch is on (where applicable) and check:
   - AC Power Indicator - Illuminates
   - Battery Operation Indicator - Extinguishes.

2. Unplug AC Power cord from the AC power source and check:
   - AC Power Indicator - extinguishes
   - Six pulses of the audio Alarm - sound **[v2.xx ONLY]**.
   - Battery operation indicator - illuminates **[v2.xx ONLY]**.

3. Reconnect the AC Power cord to the AC power source.

NORMAL MODE TESTS

1. Open the access door for both channels and check:
   - The pumping mechanisms home.

2. Install the prepared GEMINI set in channel A and close the door. Ensuring the fluid level in the container is 24" above the height of the strain beam.

3. Press ACCESS CHANNEL A **[V2.xx]** or CHANNEL SELECT A **[V3.XX]**
   - Channel A select LED - illuminates.
   - "SELECT P/C MODE" scrolls once.

CONTROLLER MODE

4. Use P/C MODE control to select Controller mode:
   - Controller mode operating indicator illuminiates.

5. Press RATE control and check:
   - Last confirmed rate or "0" flashes in the rate display
   - "SET RATE" scrolls continuously.

6. Use data entry controls to set rate to 125 Ml/hr.
   - New rate flashes in rate display
   - "SET VTBI" scrolls continuously.

7. Press VTBI control and check:
   - Last confirmed VTBI or "0" flashes in the VTBI display.

8. Use data entry controls to set VTBI to 50 mL.

9. Press START control and check:
   - Pumping mechanism operates
   - Controller mode operating indicator flashes
   - VTBI value decrements ≈2 mL/minute.

10. Use the Hemostat to pinch off the tubing above the instrument and check:
    - "LOW FLOW" advisory - scrolls
    - Audio advisory - sounds
    - After 1 minute, "OCCLUSION" alarm scrolls
    - Controller mode ALARM indicator - flashes
    - Alarm audio - sounds.

11. Clear occlusion (remove hemostat), press ACCESS CHANNEL A **[v2.xx]** or CHANNEL

SELECT A [v3.xx], then press START and check:
- Pumping mechanism - operates
- Operating indicator - flashes
- Alarm indicator - extinguishes.

12. Use hemostat to close off distal tubing and check:
    - "LOW FLOW" advisory scrolls, followed by "OCCLUSION" alarm
    - Controller mode ALARM indicator - flashes
    - Alarm audio - sounds.

13. Clear occlusion (remove hemostat), press ACCESS CHANNEL A [v2.xx] or CHANNEL SELECT A [v3.xx], then press START and check:
    - Pumping mechanism - operates
    - Operating indicator - flashes
    - Alarm indicator - extinguishes

PUMP MODE

14. Press ACCESS CHANNEL A [v2.xx] or CHANNEL SELECT A [v3.xx], then press P/C MODE control and change delivery mode to Pump:
    - Pump mode operating LED - illuminates

15. Press START control and check:
    - Pump mode operating indicator - flashes.

16. Use the hemostat to close off the proximal tubing and check:
    - "OCCLUDED-FLUID SIDE" alarm - scrolls
    - Pump mode ALARM indicator - flashes
    - Alarm audio - sounds
    - Pumping mechanism - stops

17. Clear occlusion (remove hemostat), press ACCESS CHANNEL A [v2.xx] or CHANNEL SELECT A [v3.xx], then press START and check:
    - Pumping mechanism - operates
    - Operating indicator - flashes
    - Alarm indicator - extinguishes

18. Use the hemostat to close off the distal tubing and check:
    - "OCCLUDED-PATIENT SIDE" alarm - scrolls
    - Pump mode ALARM indicator - flashes
    - Alarm audio - sounds
    - Pumping mechanism - stops

19. Clear occlusion (remove hemostat), press ACCESS CHANNEL A [v2.xx] or CHANNEL SELECT A [v3.xx], then press START and check:
    - Pumping mechanism - operates
    - Operating indicator - flashes
    - Alarm indicator - extinguishes

20. Use the 100 µL gas tight syringe to inject a 100 µL air bolus into the set's upper injection site, then check:
    - "AIR IN LINE" alarm - scrolls
    - Pump mode ALARM indicator - flashes
    - Alarm audio - sounds
    - Pumping mechanism - stops

NOTE

Air bolus must be intact when entering the AIL detector.

PUMP PRESSURE TEST

1. Power down the PC-2 and re-initialize instrument in the Maintenance Mode. For PC-2's configured with software version 2.13 connect the Maintenance Plug to the Nurse Call receptacle on the rear panel (see Figure 2-4). For all other versions, press and hold the COMPUTER CONTROL/MONITOR switch. Then press POWER ON.

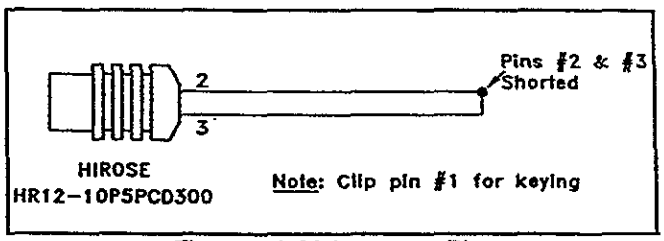


Figure 2-4. Maintenance Plug

2. Connect the distal tubing to the 60 psi pressure gauge.

3. Press Audio Control switch [v2.13] or COMPUTER CONTROL/MONITOR switch [v2.34 & Sub.] to select "pump test".

4. Press START control twice.

5. Verify rate set to 125 mL/hr and VTBI >25 mL.

6. Press START control and allow the pump to operate for at least 30 seconds and wait until the peak pressure stabilizes.

7. Record the highest pressure reading obtained. **Resultant pressure must be ≥17 psi.**

COMMUNICATIONS TEST

1. Use the Audio Control **[v2.13]** or COMPUTER CONTROL/MONITOR switch **[v2.34 & Sub.]** to select "serial port tests".
2. Connect the Communications Emulator Plug to the RS-232-C Data Port.
3. Press START control and check:
   - "echo" message - displays steadily.
4. Press START control and check:
   - Channel B Operator Information (Status/Alarm) display - sequentially displays each character of the available character set combined with a "?"
   - Upon satisfactory completion of the character set stream "OKAY" appears in the Operator Information (Status/Alarm) display
   - In the event of a failure at any point in the test, the failed character plus "?" appears in the Operator Information (Status/Alarm) display and "FAIL" appears in the VTBI display.
5. To re-run the test, press CLEAR/SILENCE control to clear the VTBI display. Check "echo" message reappears in the Operator Information (Status/Alarm) display, then Press START control to re-initiate the test.
6. Use the AUDIO CONTROL switch **[v2.13]** or COMPUTER CONTROL/MONITOR switch **[v2.34 & Sub.]** to exit the Serial Port Test and select "powerdown test".
7. Press PAUSE/STOP control to exit Maintenance mode and power down the instrument.
8. Remove the Communications Emulator plug from the RS-232-C Data Port.

WARNING

The following step must be performed on instruments configured with software version 2.13 prior to initial issue or returning the instrument to patient care.

9. Remove the Maintenance Plug from the Nurse Call/Maintenance Plug receptacle.

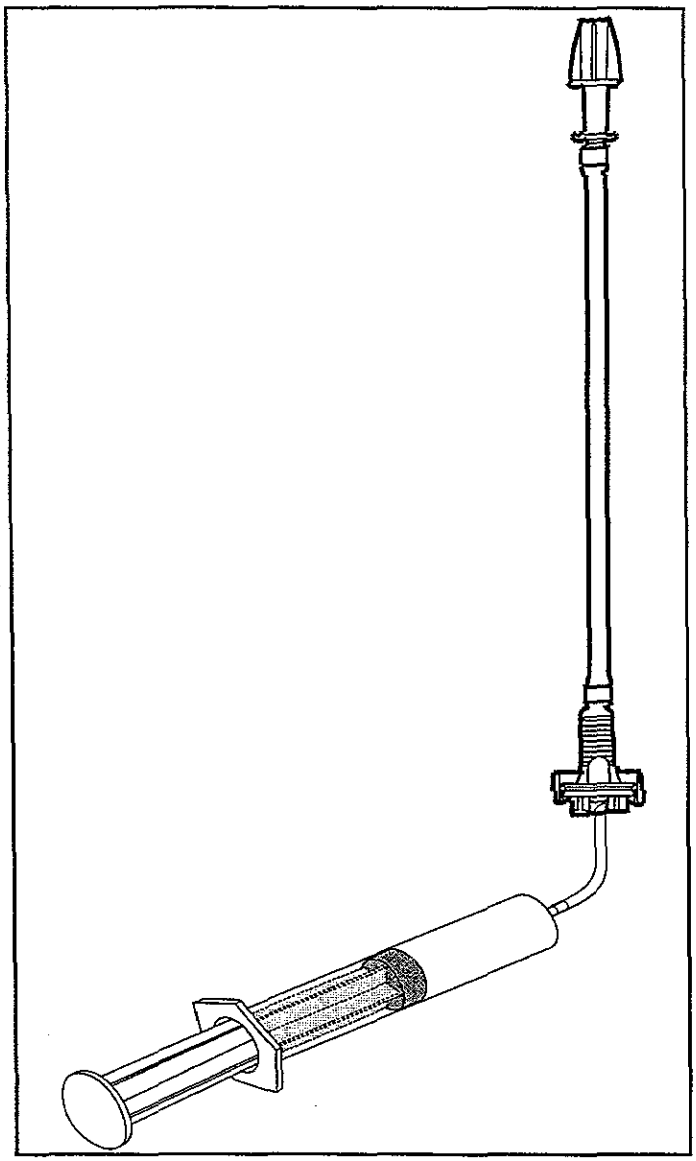


Figure 2-5. Air-In-Line Simulator

PC-2 TEST DATA SHEET

Instrument Serial No. _____ Software Version_____

Date _____ Technician_____

Test No.	Description	Reference	Pass/Fail
1	Electrical Leakage Test	2.3.2.1	____/____
2	Electrical Ground Test	2.3.2.2	____/____
3	Initialization	2.3.3.2	____/____
4	Keypad and Display Check	2.3.3.2	____/____
5	Controller Mode Operation	2.3.3.2	Ch A ____/____ Ch B ____/____
6	Pump Mode Operation	2.3.3.2	Ch A ____/____ Ch B ____/____
	Air-in-line	2.3.3.2	Ch A ____/____ Ch B ____/____

Figure 2-6. PC-2 Test Data Sheet

SECTION 3 - OPERATION

3.1 INTRODUCTION

This section describes the recommended procedures for operation of the IMED® GEMINI PC-2 Volumetric Infusion Pump/Controller ("PC-2").The information is intended to provide maintenance technicians with a basic understanding of instrument operation including the audio alerts and visual displays.

NOTE

Although the PC-2 is built and tested to exacting specifications, it is not intended to replace the role of medical personnel in the supervision of IV infusions. The user is urged to exercise vigilance in the utilization of the PC-2.

3.2 CONTROLS AND INDICATORS

The controls and indicators used to set up and operate the PC-2 are illustrated in Figure 3-1 with the functional descriptions listed in Table 3-1.

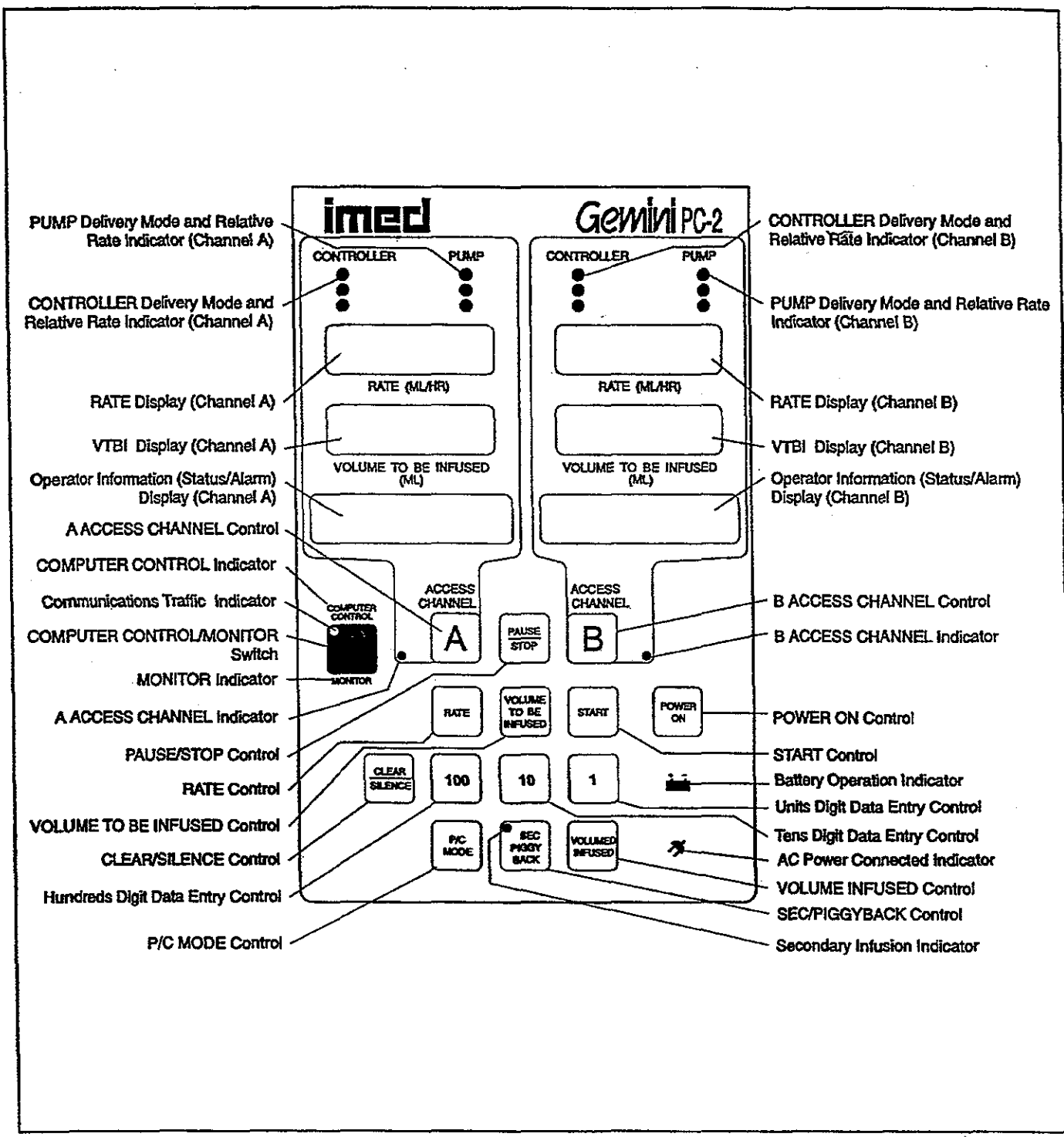


Figure 3-1. PC-2 Integer Keypad Front Panel Controls and Indicators

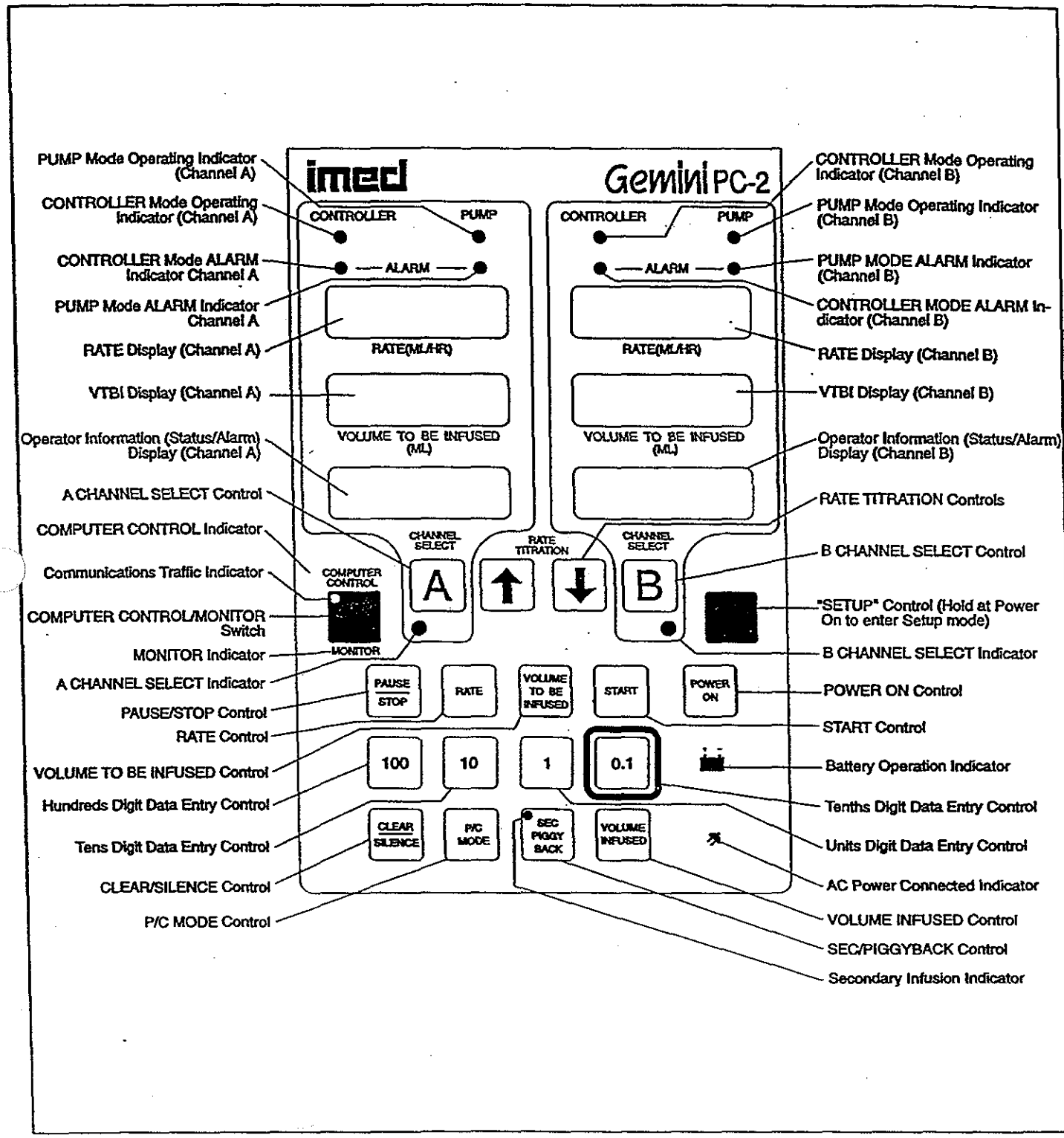


Figure 3-1a. PC-2 Fractional Keypad Front Panel Controls and Indicators

Table 3-1. PC-2 Controls and Indicators - Functional Description

Control/Indicator	Functional Description
FRONT PANEL	
Integer Keypad/Series v2.xx Software CONTROLLER Delivery Mode & Relative Rate Indicators Channel A or B	Three element LED indicators. Upper LED illuminates when the channel is activated and Controller delivery mode selected. When infusing, LEDs flash sequentially at a rate corresponding to pump operating rate.
Integer Keypad/Series v2.xx Software PUMP Delivery Mode & Relative Rate Indicators Channel A or B	Three element LED indicators. Upper LED illuminates when the channel is activated and Pump delivery mode selected. When infusing, LEDs flash sequentially at a rate corresponding to pump operating rate.
Fractional Keypad/Series v3.xx Software CONTROLLER and PUMP mode operating indicators Channel A or B	Discrete LED indicator. Illuminates steadily to indicate the delivery mode selected for that channel; flashes when the respective channel is infusing.
Fractional Keypad/Series v3.xx Software CONTROLLER and PUMP mode ALARM indicators Channel A or B	Discrete LED indicator. Flashes when the respective channel is in an alarm condition.
RATE Displays Channel A or B	Four digit, eight segment LED Displays. Displays rate infusion parameter for selected operating state (Primary or Secondary). Steady "0" displays after ACCESS CHANNEL control pressed. Flashes last confirmed rate when RATE control actuated. Display changes to steady illumination when values are confirmed by subsequent keypad action.
Volume to be Infused (VTBI) Displays Channel A or B	Four digit, eight segment LED Displays. Displays VTBI infusion parameter for selected operating state (Primary or Secondary). Steady "0" displays after ACCESS CHANNEL control pressed. Flashes last confirmed VTBI when VTBI Control actuated. Display illuminates steadily when values are confirmed. Flashes Total Volume Infused for ≈6 seconds following actuation of the VOLUME INFUSED control for channel(s) operating in Primary and Secondary Volume Infused when VOLUME INFUSED is actuated while a channel(s) is operating in Secondary.
Operator Information (Status/ Alarm) Displays Channel A or B	Eight position dot-matrix displays. Scrolls PROMPT, ADVISORY, ALARM and MALFUNCTION messages during Normal operation. Presents scrolled and/or static Maintenance mode test selections, conditions and status reports.
COMPUTER CONTROL Indicator	Backlighted indicator. Flashes when the PC-2 is enabled for computer control operation. Illuminates steadily when computer control is established.
COMPUTER CONTROL/MONITOR Switch	Alternate action type switch. When pressed, selects either Monitor or Computer Control operating condition. Operable only when the computer interface cable is connected.

Table 3-1. PC-2 Controls and Indicators - Functional Description

Control/Indicator	Functional Description
	Software Release V2.33 and Sub. When used in conjunction with the POWER ON control, enables the instrument in the Maintenance Mode [v2.xx] or Diagnostic Mode [v3.xx] and is used to step between maintenance mode test routines.
MONITOR Indicator	Backlighted indicator. Illuminates when the communication interface cable is connected to the RS-232-C Communications Data Port.
Communications Traffic Indicator	LED indicator. Flashes when communications traffic through the RS-232-C data link is active. Operable only during Monitor and Computer Control operation.
ACCESS CHANNEL A or B [V2.XX] or CHANNEL SELECT A or B [v3.xx] Controls	Alternate action type switches. When pressed, enables a channel for programming of Primary and/or Secondary infusion parameters plus Start, Pause and Stop actions.
Channel A or B Access Indicators	LED indicators. Illuminate when channel is selected for programming and operational control.
Fractional Keypad/Series v3.xx Software RATE TITRATION controls	Single or Continuous action type switch. When pressed, will increase or decrease the rate parameter 1 mL/hr (MACRO mode) or 0.1 mL/hr (MICRO mode) with each keypress or will scroll the rate up or down on the selected channel when pressed and held.
Fractional Keypad/Series v3.xx Software "SETUP" control	Momentary contact type switch. Used by biomedical and other specifically trained personnel to configure the instrument for specific operating modes.
PAUSE/STOP Control	Momentary contact type switch. When actuated once puts the selected channel into the Pause condition, if infusing pumping will stop. After 2 minutes in Pause the "PRESS START" visual and audio prompt will initiate. A second actuation shuts down the selected channel. If only one channel is active the second actuation will power down the PC-2. When pressed during a software-detected system malfunction, it will power down the PC-2.
RATE Control	Momentary contact type switch. When pressed, enables entry, change or clearing of the rate infusion parameter for the selected channel.
VOLUME TO BE INFUSED (VTBI) Control	Momentary contact type switch. When pressed, enables entry, change or clearing of the VTBI infusion parameter for the selected channel.
START Control	Momentary contact type switch. When pressed, starts the pumping mechanism for the selected channel.

Table 3-1. PC-2 Controls and Indicators - Functional Description

Control/Indicator	Functional Description
POWER ON Control	Momentary contact type switch. When pressed, applies electrical power to the PC-2. In the event of a hardware malfunction, identified by continuous audio, actuating POWER ON will shut off electrical power to all circuits and discontinue audio alarm.
Software Release V2.13 CLEAR Data Entry Control	Momentary contact type switch. When pressed following actuation of the RATE, VTBI or VOLUME INFUSED controls, clears the corresponding display for the selected channel.
Software Release V2.33 and Sub CLEAR/SILENCE Data Entry Control	Momentary contact type switch. When pressed following actuation of the RATE, VTBI or VOLUME INFUSED controls, clears the corresponding display for the selected channel. When pressed during an alarm condition, will silence the alarm for 2 minutes (when permitted).
Hundreds & Thousands (100) Digit Data Entry Control	Momentary contact type switch. Single actuation subsequent to actuating the RATE or VTBI controls increments the hundreds digit of the corresponding display for the selected channel. When pressed and held, causes the VTBI hundreds digit to carry over to the thousands digit on each passage of 9.
Tens (10) Digit Data Entry Control	Momentary contact type switch. When pressed subsequent to actuation of the RATE or VTBI control, increments the tens digit of the corresponding display for the selected channel. Display rolls over 9 to 0.
Units (1) Digit Data Entry Control	Momentary contact type switch. When pressed subsequent to actuation of the RATE or VTBI control, increments the units digit of the corresponding display for the selected channel. Display rolls over 9 to 0.
Fractional Keypad/Series v3.xx Software Tenths (0.1) Digit data entry control	Momentary contact type switch. When pressed, increments the tenths digit of the RATE or VTBI infusion parameter on the selected channel for the selected parameter (not functional in MACRO delivery). Display rolls over from 9 to 0.
Battery Operation Indicator	Backlighted indicator. Illuminates steadily when the PC-2 is operating on battery power.
P/C (Delivery) MODE Control	Alternate action type switch. When pressed, changes the delivery mode between Pump and Controller for the selected channel.
SEC/PIGGYBACK Control	Alternate action type switch. When pressed, enables the selected channel in the Secondary state allowing Secondary infusion parameters to be programmed and a Secondary infusion to be initiated.

Table 3-1. PC-2 Controls and Indicators - Functional Description

Control/Indicator	Functional Description
Sec/Piggyback Indicator	LED indicator. Flashes when the selected channel is in the Secondary state. Illuminates steadily when the selected channel is performing a secondary infusion.
VOLUME INFUSED Control	Momentary contact type switch. When actuated with neither channel selected will cause channel(s) in Primary to flash the Total Volume Infused for 6 seconds on the VTBI display and scroll "TOTAL VOL INFUSED" once; channel(s) in Secondary will flash Secondary Volume Infused for 6 seconds on the VTBI display and scroll "SEC VOL INFUSED" once. When actuated with a channel selected will display the appropriate Volume Infused and Advisory message for the mode of operation and enable the respective register for resetting to "0".
AC Power Connected Indicator	Backlighted Indicator. Illuminates when the PC-2 is connected to an external AC power source.
REAR PANEL	
Integer Keypad/Series v2.xx Software AUDIO CONTROL	When rotated, adjusts audio output volume (when permitted). Software Release V2.13 ONLY When pressed, temporarily silences audio alarm for 2 minutes (when permitted). Used to step between maintenance mode test routines.
Fractional Keypad/Series v3.xx Software AUDIO/TAMPER-RESISTANT CONTROL (on rear panel)	Dual action switch/potentiometer. When rotated, varies the audio volume; when pressed, silences audio alarm for ≈2 minutes; when pressed and held for 3 seconds with the tamper-resistant feature enabled, will lock out all of the keypad controls except VOLUME INFUSED, SEC/PIGGYBACK and CLEAR/SILENCE; a repeat 3 second actuation will unlock the keypad controls.
AC Power Interrupt Switch (Mains Switch) (220V only, where applicable)	Rocker type switch used to apply and interrupt AC voltage to the instrument for operation of the battery charging and control circuits.

3.3 OPERATING CONDITIONS

The GEMINI PC-2 can be operated independently (Normal Operation) or as a computer controlled device (Computer Operation). Normal operation includes two patient care delivery modes - Pump and Controller plus a Maintenance [v2.xx] or Diagnostic [v3.xx] mode which is provided for use by bio-medical personnel to service the instrument. Computer operation encompasses the Monitor and Computer Control modes. Operating procedures for both normal and computer controlled operation are described in detail in paragraph 3.3.1.1 below. Maintenance/Diagnostic mode capability is addressed briefly in paragraph 3.3.2 of this section and operating details are provided in paragraph 5.3.2 of section 5.

Fractional Keypad/Series v3.xx Software
PC-2s configured with Fractional keypads and Software Release v3.xx and subsequent incorporate a Setup Mode. This mode allows biomedical and other trained personnel to enable the PC-2 in specific operating modes.

3.3.1 Normal Operation

The instrument's dual channels are identical in all respects. A common keypad is used for programming and control. Individual channel activation controls serve to interconnect the keypad with a specific channel for inputting infusion parameters, starting the instrument, pausing and/or stopping instrument operation. The following procedural steps are applicable to both channels.

Integer Keypad/Series v2.xx Software
Tamper-resistant operation is achieved through the requirement to actuate an ACCESS CHANNEL Control to enable the START, RATE, VTBI, P/C MODE and PAUSE/STOP Controls.

Fractional Keypad/Series v3.xx Software
An additional Tamper-resistant feature is enabled in the Setup Mode and actuated with the Audio Control switch to lockout all the keypad controls except VOLUME INFUSED and SEC/PIGGYBACK which permit viewing parameters and CLEAR/SILENCE to clear alarm audio when permitted.

3.3.1.1 Pump and Controller Modes

The decision to use the PC-2's Pump or Controller delivery mode for specific IV infusions resides with the patient's attending medical personnel. The instrument's occlusion parameters are predicated on the delivery mode selected and the positioning of the IV solution container to provide a nominal head height of 24 inches. With a 24 inch pressure head and the instrument operating in the Controller mode, an occlusion will be sensed when the distal tubing in-line pressure exceeds bottle height pressure ±12 inches of bottle height. In the Pump mode occlusion pressure is pre-set to 10 ±2 psi for rates >30 mL/hr. At rates <30 mL/hr occlusion pressure is rate dependent to ensure timely occlusion detection. The numbered procedural steps delineated in the following paragraphs are generic to both normal and computer operating conditions. Procedures unique to a specific operating condition(s) are enclosed in a frame.

Fractional Keypad/Series v3.xx Software
A feature in the Setup Mode allows Pump mode occlusion pressure to be locked at 10 psi for all rates. Hold SETUP key at power on to enter setup mode.

Instrument SETUP mode

Setup mode defaults	
tamper resistant	disabled
P/C mode	unlocked
10 psi mode	disabled
macro/micro mode	MIC/MAC
Primary switchover alert mode	enabled
communications setup:	
serial #	0000
baudrate	9600
parity	off
stopbits	1
language selection	english

1. Press and hold the SETUP control, then press POWER ON
   - Following self test, "SETUP PC-2 V3.xx press setup control" scrolls continuously (3.xx identifies installed software release).
2. Press SETUP control - "tamper-resistant mode" scrolls continuously
   - Press START - "enabled" or "disabled" displays statically
   - Use the ⇧ or ⇩ controls to select either "enabled" or "disabled" setting
3. Press SETUP control - "P/C mode" scrolls continuously
   - Press START - "locked" or "unlocked" displays statically on each Operator Information display
   - Selected Delivery mode indicator illuminates for each channel

- Use the [A] or [B] CHANNEL SELECT controls to toggle the respective channel between PUMP and CONTROLLER mode.
- Use the ⇧ or ⇩ controls to select either "unlocked" or "locked" setting.

4. Press SETUP control - "10 psi mode" scrolls continuously
   - Press START - "enabled" or "disabled" displays statically
   - Use the ⇧ or ⇩ controls to select either enabled or disabled setting.
5. Press SETUP control - "macro/micro mode" scrolls continuously
   - Press START - "macro", "micro mode" or "MIC/MAC" displays statically
   - Use the ⇧ or ⇩ controls to select either "macro", "micro" or "MIC/MAC".
   - "MIC/MAC" allows the PC-2 to operate in either micro or macro rates.
6. Press SETUP control - "Primary switchover alert mode" scrolls continuously
   - Press START - "enabled" or "disabled" displays statically
   - Use the ⇧ or ⇩ controls to select either "enabled" or "disabled"
7. Press SETUP control - "communications setup" scrolls continuously
   - Press START - "serial #" displays statically
   - Use 1, 10, 100 and/or CLEAR/SILENCE controls to input serial number
   - Press PAUSE/STOP - "baudrate" displays statically
   - Use the ⇧ or ⇩ controls to select baudrate (110, 300, 600, 1200, 2400, 4800, 9600)
   - Press PAUSE/STOP - "parity" displays statically
   - Use the ⇧ or ⇩ controls to select parity option (O [odd], E [even] or OFF)
   - Press PAUSE/STOP - "stopbits" displays statically
   - Use the ⇧ or ⇩ controls to select stop bit option (1 or 2).
8. Press SETUP control - "language selection" scrolls continuously
   - Press START - currently selected language displays statically
   - Use the 220V or ⇧ controls to select language option (english, german, french, italian, swedish, spanish)
9. Press SETUP control - "powerdown" scrolls continuously
   - Press START or PAUSE/STOP controls to power down
     or
10. Press SETUP control - "exit setup" scrolls continuously
    - Press START to exit setup and enter infusion Setup and Operation mode

    or
    - Press SETUP control to return to beginning of setup mode default selection.

NOTE

P/C Mode, MICRO or MACRO and 10 psi modes can be locked/unlocked independent of the SETUP mode (see page 3-18).

Infusion Setup and Operating Procedures

1. Connect the PC-2 to an external AC power source using the power cord supplied by ALARIS Medical.
2. Turn the AC Power Interrupt Switch on (**220V only, where applicable**).

> **Monitor and Computer Control Operation**
>
> a. Ensure the computer communication parameters for the host computer and the PC-2 have been set and that the communications interface cable is connected to the RS-232-C Communication Data Port connector on the rear panel of the PC-2. (Refer to the To Set Up Monitor and Computer Control Operation section of this manual).

3. Press the POWER On control.
   - Verify that all indicators illuminate, all segments of the RATE and VTBI displays illuminate ("8.8.8.8.") except channel B VTBI which displays ("8.8.8.8"), and both operator information displays show eight blocks: ▒▒▒▒▒▒▒▒

   - **Software Release v2.13**
     "PC-2 v2.xx" scrolls once across the operator information displays (2.xx represents the installed software version).

     Software Release v2.34 and Subsequent
     "PC-2 v2.xxn" scrolls once across the operator information display (2.xx represents the installed software revision and n = either "a" or "b" depending on the languages available on the EPROM. The "a" version includes English, German, French and

Spanish and the "b" version includes English, German, Italian and Swedish).

Software Release v3.xx and Subsequent
"PC-2 v3.xx" scrolls once across the operator information display (3.xx = the installed software version).

- Audio Keyclick sounds once.
- Software Release v2.13
  The upper LED position in the channel A and B delivery mode and relative rate indicators illuminate according to the previously selected delivery mode.

NOTE

After 2 minutes, the PC-2 will automatically shutdown unless the ACCESS CHANNEL A or B control is pressed.

Software Release 2.34 and Subsequent
The upper LED position in the channel A delivery mode/relative rate indicator illuminates corresponding to the last selected delivery mode and the channel A RATE and VTBI displays show "0".

Software Release 3.xx and Subsequent
The Operating indicator illuminates for the last selected delivery mode.

NOTE

After 2 minutes the PC-2 will automatically shutdown unless an ACCESS CHANNEL control, the COMPUTER CONTROL MONITOR switch or the P/C MODE control is actuated or if the instrument is in alarm.

Monitor and Computer Control Operation
MONITOR indicator illuminates.

4. Prepare the IV fluid container following accepted hospital procedure.
5. Open the GEMINI administration set package, remove set, and close the roller clamp.
6. Insert the set spike into the fluid container and hang the IV container 24 inches above the instrument following accepted hospital procedure.
7. Fill the drip chamber approximately 2/3 full.
8. Open the roller clamp slowly to prime and clear all air from the injection sites and tubing fitments.
9. Close the roller clamp.
10. Open the door and press the upper tubing fitment into the recess above the pump mechanism. Using care to avoid stretching the pumping segment, insert the Flo-Stop® fitment into the AIL/SCD recess below the pump mechanism with the arrow pointing into the pump. Press the tubing into the air-in-line detector. Close the door. Follow the specific instructions included with the set.
11. Open the roller clamp.
12. Press the appropriate ACCESS CHANNEL/CHANNEL SELECT control.

    Software Release V2.13
    - The channel access indicator illuminates.
    - The RATE and VTBI displays show "0".
    - The "SELECT P/C MODE" prompt scrolls once followed by a continuous, alternating scroll of the "SET RATE" and "SET VTBI" prompts.
    - An audio prompt sounds repeatedly after 12 seconds.
    - The other channel display goes blank, if not in use.

    Software Release V2.34 and Subsequent
    - The channel access indicator illuminates.
    - The "SELECT P/C MODE" prompt scrolls once (if the P/C MODE lockout feature has not been invoked), followed by continuous scrolling of the "SET RATE" prompt.
    - An audio prompt sounds repeatedly after 12 seconds.
13. Press the P/C MODE control to change delivery mode if desired.

NOTE

The P/C Mode selection is not available on instruments with software release V2.34 and subsequent installed, when the P/C Mode lockout feature has been invoked.

- The appropriate delivery mode indicator illuminates.

14. Set the rate and VTBI.

For Independent and Monitor Operation

a. Press the RATE control.
- The last entered rate flashes on the display.
- The "SET RATE" prompt extinguishes.

b. Use the appropriate data entry controls to change rate.
- The new rate flashes on the display.

c. Press the VTBI control.
- The new rate displays steadily on the display.
- The last entered VTBI flashes on the display.
- The "SET VTBI" prompt extinguishes.
- The "PRESS START" prompt continuously scrolls after 5 seconds.
- The audio prompt is suppressed for 12 seconds.

d. Use the appropriate data entry controls to change VTBI.
- The new VTBI flashes on the display.
- The audio prompt is suppressed for 12 seconds.

NOTE

A VTBI selection of "ALL" is only to be used in conjunction with the empty container detector (ECD).

Computer Control Operation

a. The rate and VTBI are set by the host computer.

15. Attach the set to the patient's indwelling venipuncture device following accepted hospital procedure.

For Independent and Monitor Operation

16. Press the START control.
- The delivery mode and infusion parameters are entered.
- The infusion is started.
- The channel access indicator extinguishes.
- The VTBI displays steadily on the display.
- The "PRESS START" prompt extinguishes.
- The audio prompt silences.
- The delivery mode and relative rate indicators flash sequentially according to the delivery mode and the rate selected.

Verify the delivery mode/relative rate [v2.xx] or operating [v3.xx] indicators are flashing. This is the positive indication that the instrument is infusing.

Computer Control Operation

17. Press the COMPUTER CONTROL/MONITOR switch.
- The COMPUTER CONTROL indicator flashes and the MONITOR indicator extinguishes.
- When 2-way communications between the host computer and the PC-2 are established, the COMPUTER CONTROL indicator illuminates steadily.
- **The host computer starts the infusion. The infusion cannot be started from the PC-2.**
- The delivery mode and relative rate indicators flash sequentially according to the delivery mode and the rate selected.

Monitor and Computer Control Operation

- The communication traffic indicator flickers when communication between the host computer and the pump/controller is active.

During infusion:

- The VTBI decrements.
- The volume infused increments (not displayed).
- Various Advisories, Alarms, and Malfunctions may be displayed. Refer to the Operator Information Display And Alarm Response Procedures section in this manual for an explanation and appropriate response.

Upon completion of the infusion:

- An audio prompt sounds.
- The "INFUSION COMPLETE-KVO" or the "EMPTY CONTAINER-KVO" advisory, as appropriate, scrolls continuously across the display.
- A 1 or 0.x mL/hr KVO infusion is initiated.
- The RATE display shows the KVO rate of "1" mL/hr (MACRO) or 0.x mL/hr (MICRO).
- The delivery mode and relative rate indicators flash according to the delivery mode and KVO rate.

NOTE

The following detailed operating procedures apply to Pump and Controller delivery mode operations for both channels in the Independent and Monitor operating conditions only. Corresponding procedures during Computer Control are performed via the host computer.

Pausing an Infusion

1. Press the appropriate ACCESS CHANNEL [v2.xx] or CHANNEL SELECT [V3.xx] control.
   - The PC-2 continues to operate at the last entered delivery mode and infusion parameters.
   - The RATE display steadily displays the previously set rate.
   - The VTBI display steadily displays the current decremented VTBI.

2. Press the PAUSE/STOP control once.
   - The infusion stops.
   - The delivery mode and relative rate indicators illuminate steadily according to the delivery mode selected.
   - The audio prompt silences (if active).
   - An audio advisory sounds repeatedly after 15 seconds.
   - The "SET RATE" or "SET VTBI" prompts extinguish.
   - The "PAUSE" advisory continuously scrolls.
   - The "PRESS START" prompt continuously scrolls, the audio advisory extinguishes, and an audio prompt sounds after 2 minutes.

3. Press the START control to resume the infusion.
   - The infusion is resumed.
   - The "PAUSE" advisory extinguishes.

Stopping a Primary Infusion

1. Press the appropriate ACCESS CHANNEL [v2.xx] or CHANNEL SELECT [V3.xx] control.
   - The PC-2 continues to operate at the last entered delivery mode and infusion parameters.
   - The RATE display steadily displays the previously set rate.
   - The VTBI display steadily displays the current decremented VTBI.

2. Press the PAUSE/STOP control twice.
   - The infusion stops.
   - The delivery mode and relative rate indicators extinguish.
   - The channel access indicator extinguishes.
   - The "PRESS START" prompt extinguishes.
   - The "PAUSE" advisory extinguishes.
   - Any audio advisory silences.
   - All displays for the appropriate channel extinguish.
   - If this is the only active channel, the PC-2 will automatically powerdown.
     - Channel A operator information display steadily displays "POWER".
     - Channel B operator information display displays "OFF n", where "n" represents the count down to power off in seconds.
     - The display counts down from "5" to "1". One second after the display reaches "1", the PC-2 automatically powers down.

Changing Rate or VTBI During Infusion

1. Press the appropriate ACCESS CHANNEL [v2.xx] or CHANNEL SELECT [V3.XX] control.
   - The PC-2 continues to operate at the previously entered delivery mode and infusion parameters.
   - The RATE display steadily displays the previously entered rate.
   - The VTBI display steadily displays the current decremented VTBI.

2. Press the RATE control to change rate.
   - The last entered rate flashes on the display.

3. Use the appropriate data entry controls to change rate.
   - The new rate flashes on the display.

4. Press the VTBI control to change VTBI.
   - The current decremented VTBI flashes on the display.
   - The new rate displays steadily on the display.

5. Use the appropriate data entry controls to change VTBI.
   - The new VTBI flashes on the display.

6. Press the START control.
   - The new infusion parameters are entered.
   - The infusion is started at the new infusion parameters.

- The new rate or VTBI displays steadily on the displays.

Titrating Rate
Fractional Keypad/Series v3.xx Software

1. Press the appropriate CHANNEL SELECT control.
2. Press the ⇧ or ⇩ control to change the rate parameter in 1 or 0.1 mL/hr increments
   or
   Press and hold the ⇧ or ⇩ control to scroll to a new rate parameter.
   - The new rate display will begin flashing ≈0.5 seconds after the last input
   - After 5 seconds, the "PRESS START" prompt starts scrolling.
3. Press START control.
   - The new rate is confirmed and displays steadily
   - The instrument infuses at the new rate.

Changing Delivery Mode During Infusion

NOTE

This option is not available on instruments with Software release V2.34 and subsequent installed, when the P/C Mode lockout has been invoked.

1. Press the appropriate ACCESS CHANNEL [v2.xx] or CHANNEL SELECT [V3.XX] control.
   - The PC-2 continues to operate at the last entered delivery mode and infusion parameters.
   - The RATE display steadily displays the last entered rate.
   - The VTBI display steadily displays the current decremented VTBI.
2. Press the P/C MODE control.
   - The delivery mode and relative rate indicator illuminates according to the new delivery mode selected.
   - The delivery mode and relative rate indicators continue to flash sequentially according to the previously entered delivery mode and rate.
3. Press the START control.
   - The new delivery mode is entered.
   - The infusion is started at the new delivery mode.

Restarting an Infusion Following an "Infusion Complete-KVO" or "EMPTY CONTAINER-KVO" Advisory

1. Press the appropriate ACCESS CHANNEL [v2.xx] or CHANNEL SELECT [V3.XX] control.
   - The PC-2 continues to operate at the KVO delivery mode and infusion parameters.
   - The last entered rate flashes on the display.
   - A "0" or the current decremented VTBI displays steadily on the display.
2. Press the P/C MODE control to change delivery mode.
   - The delivery mode and relative rate indicator illuminates according to the new delivery mode selected.
   - The delivery mode and relative rate indicators continue to flash sequentially according to the last entered delivery mode and KVO rate.
3. Press the RATE control to change rate.
4. Use the appropriate data entry controls to change rate.
   - The new rate flashes on the display.
5. Press the VTBI control to change VTBI.
   - A "0" or the decremented VTBI flashes on the display.
   - The new rate displays steadily on the display.
6. Use the appropriate data entry controls to change VTBI.
   - The new VTBI flashes on the display.
7. Press the START control.
   - The new delivery mode or infusion parameters are entered.
   - The infusion is started.
   - The new VTBI displays steadily on the display.
   - The "INFUSION COMPLETE-KVO" or "EMPTY CONTAINER-KVO" advisory extinguishes.

To View Volume Infused for Each Channel in its Respective Operating Mode
Software Release V2.13

1. Press the VOLUME INFUSED control.
   - Channel(s) operating in Primary will flash Total Volume Infused in the respective

VTBI display(s) for 6 seconds and "TOTAL VOL INFUSED" advisory will scroll once.
- Channel(s) operating in Secondary will flash Secondary Volume Infused in the respective VTBI display(s) for 6 seconds and "SEC VOL INFUSED" advisory will scroll once.

To View or Clear Volume Infused for Selected Channel

1. Press appropriate ACCESS CHANNEL [v2xx] or CHANNEL SELECT [V3.XX] control.
   - The PC-2 continues to operate at the last entered delivery mode and infusion parameters.
2. Press VOLUME INFUSED control.
   - If the channel is operating in Primary, Total Volume Infused will flash for 6 seconds in the VTBI display and "TOTAL VOL INFUSED" will scroll once.
   - If the channel is operating in Secondary, Secondary Volume Infused will flash for 6 seconds in the VTBI display and "SEC VOL INFUSED" will scroll once.
3. Press CLEAR control while Volume Infused display is flashing.
   - If the channel is operating in Primary, Total Volume Infused register will reset to "0".
   - If the channel is operating in Secondary, Secondary Volume Infused register will reset to "0".
4. Press START or the ACCESS CHANNEL [v2xx] or CHANNEL SELECT [V3.XX] control.

To View or Clear Total Volume Infused while Operating in Secondary.

1. Press appropriate ACCESS CHANNEL [v2xx] or CHANNEL SELECT [V3.XX] control.
   - The PC-2 continues to operate at the last entered delivery mode and infusion parameters.
2. Press SEC/PIGGYBACK control.
   - Sec/Piggyback indicator changes from steady to flashing.
   - Primary infusion parameters appear in the RATE and VTBI displays.
   - "PRIMARY" advisory scrolls continuously.
3. Press VOLUME INFUSED control.
   - Total Volume Infused flashes for 6 seconds in the VTBI display.
   - "TOTAL VOL INFUSED" scrolls once.
4. Press CLEAR while the Volume Infused display is flashing.
   - Volume Infused display resets to "0" and continues to flash for 6 seconds.
5. Press SEC/PIGGYBACK control.
   - Sec/Piggyback indicator reverts from flashing to steady.
   - Secondary infusion parameters appear in the RATE and VTBI displays.
6. Press START or the ACCESS CHANNEL [v2xx] or CHANNEL SELECT [V3.XX] control.

To View or Clear Volume Infused Display
<u>Software Release V2.34 and Subsequent</u>

1. To view Total Volume Infused, with neither channel selected, press VOLUME INFUSED control once.
   - Channel(s) infusing in primary or in primary ready condition will flash the Total Volume Infused in the VTBI display for ≈6 seconds and scroll "TOTAL VOL INFUSED" across the respective Status/Alarm display.
2. To view Secondary Volume Infused with neither channel selected, press VOLUME INFUSED control twice.
   - Channel(s) infusing in Secondary or in Secondary ready will flash the Secondary Volume Infused on the respective VTBI display(s) and "SEC VOL INFUSED" will scroll on the Status/Alarm display(s).
3. To View Total Volume or Secondary Volume Infused for a selected channel, press VOLUME INFUSED control once or twice respectively.
   - Presentation is the same as in step 1 or 2 above, except the presentation will occur for the selected channel only.
4. To clear Total and Secondary Volume Infused displays:
   - Channel to be cleared must be selected.
   - Press VOLUME INFUSED control, then press CLEAR while Volume Infused display is flashing.

- Both Volume Infused registers will clear and "0" will flash in the respective VTBI display for ≈6 seconds. "TOTAL VOL INFUSED" will scroll.

NOTE

Total volume infused includes primary plus secondary volume infused; secondary volume infused accumulates secondary infusion volume only.

Setting Up Secondary (Piggyback) Infusion With Dual Rates

1. Set up the Primary infusion (using a check valve administration set) as previously described. The Secondary infusion may be set up prior to or after starting a Primary infusion.

2. Prepare the Secondary fluid container following accepted hospital procedure.

3. Open the IMED SECONDARY administration set package, remove set, and close clamp.

4. Insert the set spike into the fluid container and hang the Secondary container following accepted hospital procedure.

5. Attach the enclosed needle to the Secondary set.

6. Fill the drip chamber approximately 2/3 full.

7. Open clamp and prime the set, then close clamp.

8. Insert the Secondary set needle into the upper injection site on the Primary set.

9. Lower the Primary fluid container using the hanger provided with the Secondary set.

10. Open the clamp on the Secondary set.

11. Press the appropriate ACCESS CHANNEL/CHANNEL SELECT control.
    - The Primary infusion continues uninterrupted.

12. Press the SEC/PIGGYBACK control.
    - The Sec/Piggyback indicator flashes.
    - The RATE and VTBI displays show "SEC".

13. Press the RATE control.
    - The last entered Secondary rate flashes on the display.

14. Use the appropriate data entry controls to change Secondary rate.
    - The new Secondary rate flashes on the display.

15. Press the VTBI control.
    - The last entered Secondary VTBI or the current decremented Secondary VTBI flashes on the display.
    - The new Secondary rate displays steadily on the display.

16. Use the appropriate data entry controls to change Secondary VTBI.
    - The new Secondary VTBI flashes on the display.

NOTE

"ALL" is not an allowable VTBI for a dual rate Secondary (Piggyback) infusion. Do not use an ECD with a Secondary administration set.

Verify that the VTBI setting does not exceed the contents of the Secondary fluid container.

17. Press the START control.
    - The Secondary delivery mode and infusion parameters are entered.
    - The Secondary infusion is started.
    - The "SECONDARY" advisory continuously scrolls.
    - The Sec/Piggyback indicator illuminates steadily.
    - The Secondary VTBI displays steadily on the display.

During Secondary Infusion:

- The Secondary VTBI decrements.
- The Secondary volume infused increments.

Upon completion of the Secondary infusion:
- The audio alarm sounds six times (may be disabled in v3.xx).
- The PC-2 automatically switches over to the Primary infusion parameters.

- The preset Primary rate and VTBI display steadily on the displays.
- The Sec/Piggyback indicator extinguishes.
- The "SECONDARY" advisory extinguishes.
- The "PRIMARY" advisory continues to scroll.
- The mode and relative rate indicators change to reflect the Primary infusion delivery mode and rate.

NOTE

Actual changeover from the Secondary to the Primary IV solution is accomplished independently of pump/controller operation and occurs when the fluid level in the Secondary container drops to the same level as the fluid in the Primary administration set drip chamber.

Viewing Primary Infusion Parameters During Secondary Infusion

1. Press SEC/PIGGYBACK control
   - Primary RATE and VTBI parameters will flash on the respective displays for =6 seconds.

Changing Primary Infusion Parameters During Secondary Infusion

1. Press the appropriate ACCESS CHANNEL [v2.xx] or CHANNEL SELECT [V3.XX] control.
   - The Secondary infusion continues uninterrupted.
   - The last entered Secondary rate displays steadily on the display.
   - The current decremented Secondary VTBI displays steadily on the display.
2. Press the SEC/PIGGYBACK control.
   - The last entered Primary rate and VTBI flash on the displays.
3. Press the RATE control to change Primary rate.
4. Use the appropriate data entry controls to change Primary rate.
   - The new Primary rate flashes on the display.
5. Press the VTBI control to change Primary VTBI.
6. Use the appropriate data entry controls to change Primary VTBI.
   - The new Primary VTBI flashes on the display.
7. Press the appropriate ACCESS CHANNEL [v2xx] or CHANNEL SELECT [V3.XX] control.
   - The new Primary delivery mode and infusion parameters are entered.

Stopping a Secondary Infusion and Returning to Primary Infusion

1. Press the appropriate ACCESS CHANNEL [v2.xx] or CHANNEL SELECT [vV3.XX] control.
   - The Secondary infusion continues uninterrupted.
   - The current decremented Secondary VTBI displays steadily on the display.
   - The last entered Secondary rate displays steadily on the display.
2. Press the SEC/PIGGYBACK control.
3. Press the START control.
   - The Secondary infusion stops.
   - The audio alarm sounds six (6) times (may be disabled in v3.xx)
   - The Primary infusion starts.
   - The Primary rate and VTBI display steadily on the displays.

NOTE

If the ACCESS CHANNEL [v2.xx] or CHANNEL SELECT [V3.XX] control is pressed rather than the START control, the change from Secondary infusion to Primary infusion will be cancelled and the Secondary infusion will continue.

Infusing Using an Empty Container Detector (ECD)

1. Set up a Primary infusion on either channel.
2. Connect an ECD to the appropriate ECD connector on the rear panel of the PC-2 and attach the ECD sensor to the drip chamber of the Primary set.
3. Set the Primary VTBI to "All" by clearing the VTBI and pressing the 1 (MACRO) or 0.1 (MICRO) data entry control once.

4. Press the START control.

When the ECD senses an empty container:

- An audio prompt sounds.
- The "EMPTY CONTAINER-KVO" advisory scrolls continuously across the display.
- A 1 or 0.x mL/hr KVO infusion is initiated.
- The RATE display shows the KVO rate of "1" or "0.x" mL/hr.
- The delivery mode and relative rate indicators flash according to the delivery mode and KVO rate.

Clearing Alarms

1. Check the operator information display to determine which channel is alarming and the type of alarm condition.

2. Refer to the Operator Information Display and Alarm Response Procedures section in this manual for the proper procedures for responding to a specific alarm condition.

TURNING OFF THE PC-2

For Independent and Monitor Operation

1. Press the appropriate ACCESS CHANNEL control.
   - The channel access indicator illuminates.

2. Press the PAUSE/STOP control twice to terminate an active infusion.
   - The channel access indicator extinguishes.
   - The infusion stops.
   - The channel shuts down.

3. Repeat steps 1 and 2 if both channels are infusing.

During power off sequence:

- Channel A operator information display steadily displays "POWER".
- Channel B operator information display displays "OFF n", where "n" represents the count down to power off in seconds.
- The display counts down from "5" to "1" [v2.xx] or "3" to "1" [v3.xx]. One second after the display reaches "1", the PC-2 automatically powers down.

Computer Control Operation

1. Press the COMPUTER CONTROL/MONITOR switch.
   - The COMPUTER CONTROL indicator extinguishes.
   - The MONITOR indicator illuminates.

2. Press the appropriate ACCESS CHANNEL control.
   - The channel access indicator illuminates.

3. Press the PAUSE/STOP control twice to terminate an active infusion.
   - The channel access indicator extinguishes.
   - The infusion stops.
   - The channel shuts down.

4. Repeat steps 1 through 3 if both channels are infusing.

NOTE

To interrupt the power down sequence, press the ACCESS CHANNEL [v2xx] or CHANNEL SELECT [V3.xx] A or B control prior to the count-down timer in the channel B operator information display reaching "1".

In the event of a hardware-detected malfunction (evidenced by constant audio), the POWER ON control must be pressed to silence the audio and interrupt instrument electrical power. Pressing the POWER ON control a second time will re-power the instrument and allow normal shut down procedures to be employed. If the malfunction can not be circumvented, the instrument will require technical personnel to silence the alarm and deactivate the electrical circuit.

In the event of a software-detected malfunction, i.e. a HELP message appearing in the operator information display, the PC-2 must be turned off by pressing the PAUSE/STOP control.

Software Revision V2.34 and Subsequent

Locking and Unlocking the P/C MODE Control

1. To Lock - while depressing the P/C MODE control, press POWER ON to initialize the instrument. The delivery mode previously selected will be Locked-in.

2. To Unlock - powerdown the instrument, depress the P/C MODE control and press POWER ON to initialize. The P/C MODE control will be restored to normal operation.

Fractional Keypad/Series v3.xx Software

Locking and Unlocking the MICRO Delivery Mode

1. To Lock - With the instrument off, press and hold the tenths (0.1) key then press POWER ON. After initialization release the tenths key:
   - "MICRO" message will scroll following the "SELECT P/C MODE" message or "PC-1 Vx.xx" if P/C Mode lockout is invoked.
   - "MICRO" message will cancel once the RATE control has been pressed.
   - RATE and VTBI displays will appear in the "0.0" format.

2. To Unlock - With the instrument off, press and hold the tenths (0.1) key then press the POWER ON control. Following initialization release the tenths key:
   - The instrument is now in UNIVERSAL mode.
   - RATE and VTBI displays will appear in either the "0.0" or "0" format depending upon the Universal mode rate and VTBI parameters selected.

Locking and Unlocking the MACRO Delivery Mode

1. To Lock - With the instrument off, press and hold the hundreds (100) key then press POWER ON. Following initialization release the hundreds key:
   - "MACRO" message will scroll following the "SELECT P/C MODE" message or "PC-1 Vx.xx" if P/C Mode lockout is invoked.
   - "MACRO" message will cancel once the RATE control has been pressed.
   - RATE and VTBI displays will appear in the "0" format.

2. To Unlock - With the instrument off, press and hold the hundreds (100) key then press the POWER ON control. Following initialization release the hundreds key:
   - The instrument is now in UNIVERSAL mode.
   - RATE and VTBI displays will appear in either the "0.0" or "0" format depending upon the rate and VTBI parameters selected.

Locking and Unlocking the *10 psi* Mode

1. To Lock - With the instrument off, press and hold the tens (10) key then press POWER ON. After initialization release the tens key:
   - "10 psi" message will scroll until the START control is actuated.

2. To Unlock - With the instrument off, press and hold the tens (10) key then press the POWER ON control. Following initialization release the tens key.

Setting Up Monitor and Computer Control Operation

The procedures required to set up the PC-2 for Monitor and Computer Control operation are described in the following paragraphs.

Establish PC-2/Host Computer Interface

1. Set Computer Communications Parameters.

NOTE

Before the PC-2 can be used in the Monitor or Computer Control operating conditions, the computer communication parameters must be set by hospital technical personnel, both in the host computer and in the PC-2. Thorough familiarity with independent operation of the PC-2 is a prerequisite for technical personnel responsible for configuring the instrument for remote operation. The procedures for setting the computer communication parameters for the PC-2 are provided in the PC-2 Inspection, Setup and Installation Guide. The procedures for setting the computer communication parameters for the host computer are provided in the ALARIS Medical C2 Programmer's Guide.

2. Connect the Communication Interface Cable.

NOTE

Before the PC-2 can be set up for either Monitor or Computer Control operation, the communication interface cable must be connected to the RS-232-C Communication DATA PORT connector on the rear panel of the PC-2. The technical data necessary to interface the host computer interface cable to the PC-2's RS-232-C Communication DATA PORT connector is provided in the ALARIS Medical C2 Programmer's Guide.

When power is applied to the PC-2's circuits and the communication interface cable is connected, the MONITOR indicator will illuminate.

3. Refer to the Detailed Set Up and Operating Procedures section in this manual to complete the set up for a MONITOR or COMPUTER CONTROL infusion.

Changing Operating Conditions

The procedures required to change the operating condition for the PC-2 are described in the following paragraphs.

Change PC-2 Operating Condition from Independent to Monitor

1. Connect the communication interface cable to the RS-232-C communication DATA PORT connector on the rear panel of the PC-2.
   - The MONITOR indicator illuminates.

Change PC-2 Operating Condition from Monitor to Computer Control

1. Press the COMPUTER CONTROL/MONITOR switch.
   - The COMPUTER CONTROL indicator flashes and the MONITOR indicator extinguishes.
   - When 2-way communications are established and the host computer asserts control, the COMPUTER CONTROL indicator illuminates steadily.
   - **The host computer starts the infusion. The infusion cannot be started from the PC-2.**
   - The delivery mode and relative rate indicators flash sequentially according to the delivery mode and the rate selected.
   - The communication traffic indicator flickers when communication is active.

Change PC-2 Operating Condition from Computer Control to Monitor

1. Press the COMPUTER CONTROL/MONITOR switch.
   - The COMPUTER CONTROL indicator extinguishes.
   - The MONITOR indicator illuminates.

Change PC-2 Operating Condition from Monitor to Independent

1. Disconnect the communication interface cable from the RS-232-C communication DATA PORT connector on the rear panel of the PC-2.
   - The MONITOR indicator extinguishes.

3.3.1.2 Battery Powered Operation

The PC-2 will provide normal operation under battery power for a limited period of time for ambulatory use or as a backup to primary power in the event of a power interruption. Battery operating life can be extended by utilizing delivery rates with low motor current draw. The following procedures are recommended for battery powered operation:

1. By limiting delivery rate to ≤125 mL/hr, battery powered operation will support a single channel for five hours, or both channels for four hours.

NOTE

From a HELP BATTERY condition recharging to ≈90% capacity requires 4 hours with the instrument powered off and 10 hours (with dual state charger) or 18 hours (without dual state charger) with the instrument operating a single channel at ≤125 mL/hr.
Any time a LOW BATTERY advisory is displayed the battery should be fully recharged prior to subsequent battery powered instrument operation.

2. Configure the pump for operation in the same manner as for normal operation (see paragraph 3.3.1.1).

3. Actuate the POWER ON Control. All indicators and displays will react as in normal operation (see paragraph 3.3.1.1), except the Battery Operation Indicator will remain illuminated.

4. Install administration set in the pump.

5. Press an ACCESS CHANNEL [v2.xx] or CHANNEL SELECT [V3.XX] control.

6. Set Delivery Mode, Rate and VTBI in the same manner as for normal operation.

7. Press START Control.

3.3.2 Maintenance or Diagnostic Mode

The Maintenance or Diagnostic Mode is incorporated into the PC-2 to provide bio- medical personnel access to the diagnostic test routines. Entry into the Maintenance/Diagnostic Mode is accomplished by performing the following procedure:

1. Software Release V2.13
Install the maintenance plug in the Nurse Call/Maintenance Plug receptacle on the PC-2's rear panel (see figure 3-2).

Software Release V2.34 and Subsequent
Press and hold the COMPUTER CONTROL/ MONITOR switch, then perform step #2.

2. Actuate the POWER ON Control. Entry and initialization are affected. No visual prompts are presented and control passes directly to the Version Display test:

Integer Keypad/Software Release V2.13
"maintenance Vx.xx" scrolls on the Channel B Status/Alarm Display. The x.xx identifies the pump software release number.

NOTE

The maintenance plug must remain installed to change from one scrolled test string to the next and during the Motor Homing Test.

Software Release V2.34 and Subsequent
"maintenance Vx.xxn" scrolls across the Operator Information display (x.xx represents the installed software revision and 'n' represents the "a" or "b" version of the EPROM).

Fractional Keypad/Series V3.xx Software
"diagnostics PC2 v3.xx to exit press <stop>" scrolls across the channel B operator information display (3.xx represents the installed software revision).

3. Software Release V2.13
Each actuation of the AUDIO CONTROL (ACCESS) switch, or

Software Release V2.34 and Subsequent
Each actuation of the COMPUTER CONTROL/ MONITOR switch will sequentially step control from one test to the next in the following sequence:

Integer Keypad/Series v2.xx Software
- Timebase Check
- Lamp Test with Audio
- Keypad Test
- Error Log Display
- Homing Test
- Pump Test
- Serial Port Tests
- A/D Voltage Display
- Input Port Display
- C2 Communications Setup
- Language Selection(V2.34 and Sub.)
- Powerdown Test

Fractional Keypad/Series v3.xx Software
- error log display
- pump test
- motor homing test
- a/d voltage display
- input port display
- lamp test
- keypad test
- timebase check
- serial port tests
- rom crc display
- powerdown test

Each of these tests, when selected, is accompanied by a scrolled confirmation message on the Status/Alarm Display.

4. Integer Keypad/Series v2.xx Software
   Actuation of the PAUSE/STOP control while a test identifier is scrolling will interrupt the test sequence, skip the remaining tests and go to the powerdown test.

   Fractional Keypad/Series v3.xx Software
   Diagnostic mode can only be exited when the Diagnostic mode or powerdown test identifier are scrolling or via a powerdown in the Pump Test routine.

5. Each test is initiated by actuating the START control. The scrolled test identifier is replaced with a statically displayed test phase identifier. The appropriate test select control may be used at times to deselect the current test and proceed to the next test in the Maintenance/ Diagnostic mode test sequence.

3.4 OPERATOR INFORMATION DISPLAY AND ALARM RESPONSE PROCEDURES

In the normal operating mode four types of visual displays are presented to the operator: prompts, advisories, alarms and malfunctions. Several of the messages will be scrolled across the Status/Alarm Display of both channels, while others will be limited to presentation on the display for a specific channel. Under certain conditions, it is possible for one or more types of messages to be active at the same time. In that case, the messages will be sequenced such that each message will display once before any message is repeated. The display of "Volume Infused" will take precedence over prompts and advisories, but not over alarm or malfunction messages.

Table 3-2 lists the Status/Alarm Displays presented by the PC-2, identifies the probable cause and defines the recommended operator response.

The PC-2 Visual Indicator Displays have the following attributes:

RATE and VTBI Displays

Type Presentation

1 0.5 sec flash
2 Steady

STATUS/ALARM Display

3 Scroll (Across one or both channels)
4 Interrupted Scroll (Sensor initiated message takes precedence over Prompt)
5 Static (Applicable ONLY in the maintenance mode)

3.5 AUDIO ALERT SYSTEM

The PC-2 is programmed to produce six distinct audio alerts. The attributes of each are described in Figure 1-2.

3.6 NURSE CALL FEATURE

The PC-2 incorporates a Nurse Call feature that will activate an externally powered nurse call system when the instrument initiates any of the following conditions:

Alarms:	All
Malfunctions:	All
Prompts:	PRESS START
Advisories:	INFUSION COMPLETE-KVO, EMPTY CONTAINER-KVO and LOW BATTERY

Table 3-2. PC-2 Status/Alarm Displays

PROMPTS

A Prompt is a visual alert requesting the instrument operator to take a specific action.

Prompt	Meaning	Response
SELECT P/C MODE Audio: none Visual: one scroll	Begins following press of POWER ON control, if P/C Mode control is unlocked.	Select Pump or Controller delivery mode, as appropriate.
SET RATE Audio: prompt Visual: continuous scroll	Begins following press of POWER ON and ACCESS CHANNEL [v2xx] or CHANNEL SELECT [V3.XX] controls, or if START control is pressed with rate set to "0".	Press RATE control and enter rate.
SET VTBI Audio: prompt Visual: continuous scroll	Begins following press of VTBI control, or if START control is pressed with VTBI set to "0".	Press VTBI control and enter VTBI.
PRESS START Audio: prompt Visual: continuous scroll	Begins ≈5 seconds after last press of data entry controls if neither parameter is zero, or ≈12 seconds after an alarm is cleared, or ≈2 minutes after PAUSE is pressed.	Press START control.
ACCESS CHANNEL [v2.xx] or **SELECT CHANNEL** [v3.xx] Audio: none Visual: scrolls three times	Begins when attempt is made to set parameters or start infusion prior to selecting a channel.	Press appropriate ACCESS CHANNEL [v2xx] or CHANNEL SELECT [V3.XX] control.

ADVISORIES

An Advisory is a visual and audio alert to the instrument operator that an extraordinary, but non-critical condition exists, and operator action should be taken as soon as possible.

Advisory	Meaning	Response
SECONDARY Audio: changeover when SEC complete (v3.xx if enabled) Visual: continuous scroll	Secondary infusion in progress.	None.
PRIMARY Audio: none Visual: continuous scroll	SEC/PIGGYBACK pressed while operating in Secondary, or automatic changeover from Secondary to Primary has taken place.	None. (Press START to clear advisory.)
SETUP Audio: prompt Visual: continuous scroll	Instrument powered in the SETUP mode	DO NOT USE ON PATIENT. Check with Biomedical Department

Table 3-2. PC-2 Status/Alarm Displays

Advisory	Meaning	Response
INFUSION COMPLETE-KVO Audio: prompt Visual: continuous scroll	VTBI has been infused; PC-2 is infusing at KVO rate.	Turn off PC-2, or set up new infusion.
EMPTY CONTAINER-KVO Audio: prompt Visual: continuous scroll	Empty container detected by ECD before programmed VTBI delivered, or when "ALL" has been used as the VTBI infusion parameter. PC-2 is infusing at KVO rate.	Replace IV container, turn off PC-2, or set up new infusion. ECD plugged into PC-2, but not attached to drip chamber.Attach ECD to drip chamber.
LOW BATTERY Audio: prompt Visual: continuous scroll	Low battery threshold sensed, remaining battery operational life is limited.	Connect AC power cord to outlet; alarm will be silenced.
MAINTENANCE [v2.xx] Audio - beeps once Visual - continuous scroll	Instrument powered up in the maintenance mode.	**DO NOT USE ON PATIENT.** Check with Biomedical Department.
DIAGNOSTIC [v3.xx] Audio: key click Visual: continuous scroll	Instrument powered up in the DIAGNOSTIC mode.	**DO NOT USE ON PATIENT.** Check with Biomedical Department.
PAUSE Audio: advisory, then prompt after 2 minutes Visual: continuous scroll	PAUSE/STOP control has been pressed once.	Press START control to resume infusion, or press PAUSE/STOP a second time to stop infusion.
POWER OFF Audio: none Visual: static display	PAUSE/STOP control has been pressed twice.	None.
10 PSI Audio: none Visual: intermittent scroll	Pump mode is locked into 10 (±2) psi occlusion pressure at all flow rates.	None. Time to occlusion at low rates will be significantly increased.
PANEL LOCKED Audio: key click Visual: continuous scroll	When enabled, audio control has been pressed and held for 3 secs. to initiate tamper-resistant feature.	None. Repeat to cancel tamper-resistance.
LOW FLOW Audio: advisory Visual: continuous scroll	Flow has slowed due to backpressure equalling container height. An occlusion alarm will occur within one minute.	Check tubing for restriction, raise container, press START, or change to pump delivery mode (if P/C Mode control unlocked).
TOTAL VOL INFUSED Audio: none Visual: single scroll	VOLUME INFUSED control pressed once.	None; numeric value in VTBI display is cumulative.
SEC VOL INFUSED Audio: none Visual: single scroll	VOLUME INFUSED control pressed twice while in Secondary.	None. Numeric value in VTBI display reflects volume of secondary.
MACRO Audio: none Visual: continuous scroll	Can only set up using MACRO parameters.	None; PC-2 is locked in MACRO configuration.

Table 3-2. PC-2 Status/Alarm Displays

Advisory	Meaning	Response
MICRO Audio: none Visual: continuous scroll	Can only set up using MICRO parameters.	None; PC-2 is locked in MICRO configuration.

ALARMS

An Alarm condition is signaled by a combined visual and audio alert to the instrument operator that an abnormal situation exists, pumping stops on the affected channel and operator action is required immediately.

Alarm	Meaning	Response
CHECK ECD Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	START control pressed with VTBI set to "ALL" and ECD not connected, or ECD has been disconnected during an "ALL" infusion, or ECD has failed. Infusion stops.	Connect or repair ECD, or set VTBI to a value other than "ALL", then press START control.
CHECK IV SET Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Administration set not properly installed. Infusion stops.	Close roller clamp, remove and re-install administration set, close door, open roller clamp.
CLOSE DOOR Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Door opened during an infusion. Infusion stops.	Close door, press appropriate ACCESS CHANNEL [v2xx] or CHANNEL SELECT [V3.XX] control, then press START control.
AIR-IN-LINE Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Air has been detected in set during an infusion. Infusion stops.	Ensure tubing is properly installed in air-in-line detector. If air is present, clear air from administration set. Press appropriate ACCESS CHANNEL [v2xx] or CHANNEL SELECT [V3.XX] control, then press START.
OCCLUDED PATIENT SIDE Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Increased backpressure sensed while infusing in the Pump delivery mode. Infusion on affected channel stops.	Clear occlusion, press appropriate ACCESS CHANNEL [v2xx] or CHANNEL SELECT [V3.XX] control, then press START.
OCCLUDED FLUID SIDE Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Upstream occlusion sensed while infusing in Pump delivery mode. Infusion on affected channel stops.	Clear occlusion in fluid side of administration set, press appropriate ACCESS CHANNEL [v2xx] or CHANNEL SELECT [V3.XX] control, then press START.

Table 3-2. PC-2 Status/Alarm Displays

Alarm	Meaning	Response
OCCLUDED Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Occlusion is detected in either fluid or patient side while infusing in Controller delivery mode. Infusion on affected channel stops.	Clear occlusion or raise the fluid container. Press the appropriate ACCESS CHANNEL [v2xx] or CHANNEL SELECT [V3.XX] control, then press the START control. (If the occlusion recurs, open and close door. Press ACCESS CHANNEL [v2xx] or CHANNEL SELECT [V3.XX] and START).
PARTIAL OCCLUSION FLUID SIDE Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Partial upstream occlusion detected while infusing in Pump delivery mode. Infusion on affected channel stops.	Remove cause of reduced flow in fluid side of administration set, press appropriate ACCESS CHANNEL [v2xx] or CHANNEL SELECT [V3.XX] control, then press START.
"FLO STOP" OPEN/ CLOSE DOOR Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Flo-Stop open (in free flow position) with door open.	Close roller clamp on set or close door and resume infusion by pressing appropriate ACCESS CHANNEL [v2xx] or CHANNEL SELECT [V3.XX] control, then pressing START control. (If alarm occurs when the door is opened, replace PC-2 with operable unit.)
Computer Control Operation		
KVO COMM CABLE Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Communication interface cable is disconnected. Infusion(s) continue(s) at KVO rate.	Reconnect communication cable. Press COMPUTER CONTROL/ MONITOR control. Restart infusion(s) from host computer.
KVO COMM TOUT Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	Communication time-out has occurred. Infusion continues at KVO rate.	Press COMPUTER CONTROL/ MONITOR control to change PC-2 operation to MONITOR.
KVO Audio: alarm Visual: continuous scroll Channel mode Alarm indicator: flashes	A disconnected communications cable has been reconnected.	Press ACCESS CHANNEL [v2xx] or CHANNEL SELECT [V3.XX] and START to restart the interrupted infusion(s). Press COMPUTER CONTROL/ MONITOR to restore computer controlled operation.
	A communications timeout has been corrected.	Press COMPUTER CONTROL/ MONITOR control. Restart programmed infusion(s) from host computer.

Table 3-2. PC-2 Status/Alarm Displays

MALFUNCTION

A Malfunction condition is signaled by an audio alert; pumping stops on one or both channels and an Error Log message is recorded. Software detected malfunctions are accompanied by a visual "HELP" message. No visual messages accompany hardware detected malfunctions. Instruments experiencing a single channel hardware malfunction may continue to operate using the other channel. Instruments with dual channel hardware malfunctions must be taken out of service. Hardware malfunctions must be corrected by a qualified biotechnician prior to returning the instrument to service.

Malfunction	Meaning	Response
HELP INTERNAL ERROR Audio: malfunction Visual: continuous scroll and the malfunction code will display in the VTBI display Channel mode Alarm indicator: flashes	A software detected malfunction has occurred. Infusion on both channels stops.	Press PAUSE/STOP control once to turn off the PC-2. Replace the PC-2 with operable unit.

NOTE: If Malfunction Code 26 appears, immediately disconnect the AC power cord from the external power source.

HELP BATTERY Audio: malfunction Visual: continuous scroll and malfunction code "38" will display in the VTBI display Channel mode Alarm indicator: flashes	Low battery voltage detected. Infusions on both channels stop.	Connect AC power cord to power source. Press PAUSE/STOP control to turn off the PC-2. Press POWER ON, press CHANNEL SELECT, reenter rate and VTBI. Press START to resume the infusion(s).
(HARDWARE-DETECTED MALFUNCTION) Audio: malfunction Visual: none Channel mode Alarm indicator: flashes	A hardware detected malfunction has occurred. Infusion on both channels stops.	Ensure that the AC power cord is connected to an external power source. Press POWER ON control to reset the audio and turn off electrical power to the PC-2. (If audio persists, press POWER ON, then CLEAR/SILENCE. Perform normal power off procedures and replace PC-2 with operable unit.)
Software Release V2.13 only HELP RATE ACCURACY Audio - Malfunction Visual - continuous scroll	Software detected malfunction - channel failure, pumping stops on failed channel.	Press ACCESS CHANNEL for failed channel, press PAUSE/STOP twice. Continue to use other channel.

SECTION 4 - PRINCIPLES OF OPERATION

4.1 INTRODUCTION

This section describes the functional operation of the mechanical and electrical/electronic subsystems of the IMED® GEMINI PC-2® Volumetric Infusion Pump/Controller. The material is presented in a manner and format that is complementary to the troubleshooting routines delineated in Section 5 - Maintenance. The technical descriptions are referenced to the electrical schematics, mechanical diagrams and illustrated parts breakdowns presented in sections 4, 5 and 6.

The functional descriptions presented in this section are divided into two subsections. The first addresses the mechanical system operation and the second describes the electrical/electronic control circuits and operational displays. The electrical theory of operation is described in relation to the Functional Block Diagram depicted in Figure 4-2, and can be best understood by following the description on the logic diagrams, display board schematic and interconnect diagram.

4.2 MECHANICAL OPERATION

The following material is presented in a manner that assumes the reader has a basic understanding of the information provided in sections 1 through 3 of this manual and in addition has hands-on experience in setting up and operating the PC-2. Direct observation of the mechanical sequence of events that take place during instrument operation is not possible with the pumping mechanism and strain beam installed in the PC-2. However, by reading the following text while referring to the appropriate figures, a thorough understanding of the instrument's mechanical operation can be acquired.

4.2.1 Physical Description

4.2.1.1 Pumping Mechanism

The pumping mechanism assembly consists of three principle subassemblies: the stepper motor, the camshaft/pumping finger housing and the motion sensor (see Figure 4-1). The stepper motor drive shaft is connected to the camshaft by a flexible coupling. The encoder wheel of the motion sensing assembly is connected directly to the top of the camshaft. The camshaft is configured with 12 vertically staged cam lobes. The eccentric axis of each lobe is offset 30° counterclockwise from the lobe directly above. This positioning provides full forward travel for each pumping finger sequentially from top to bottom during each counterclockwise (when viewed from above) revolution of the camshaft. The cam lobes are evenly spaced except numbers 9 and 10 which are separated by 5/8" to accommodate a strain beam type pressure sensor.

4.2.1.2 Strain Beam (Pressure Transducer)

The strain beam assembly consists of the housing assembly, a strain beam and sensing finger (see Figure 4-3). The housing assembly is mounted on the front case assembly behind the urethane pump seal and is positioned between fingers 9 and 10 of the pumping mechanism. Four strain sensitive resistors are deposited on the strain beam, two on the tension section and two on the compression section.

4.2.2 Functional Operation

4.2.2.1 Pumping Mechanism

In the Normal operating mode, the PC-2 is initialized when the POWER ON control is actuated. The selected channel's pumping mechanism begins operating when an administration set is installed, 'legal' infusion

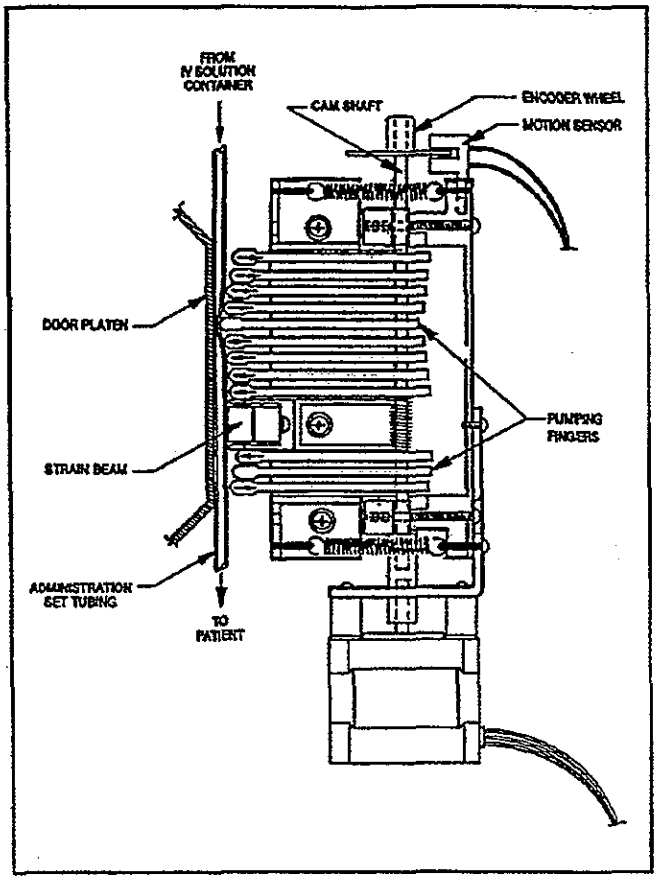


Figure 4-1. PC-2 Pumping Mechanism

parameters are programmed and the START control is actuated. The camshaft is coupled directly to the stepper motor. Stepper motor speed is variable and is proportional to the infusion rate programmed for the selected channel. Volume to be infused (VTBI) is a function of the total number of steps issued to the motor for a programmed infusion rate. The encoder wheel and motion sensor located on top of the pumping mechanism's top plate assembly provides the electronic control system with camshaft position, direction and speed of rotation. Encoder wheel position is correlated with the output of the motor control chip on the analog board to verify rate accuracy.

When an administration set is installed in the pumping chamber and the access door is closed and latched, the set's Flo-Stop is opened and the pumping segment tubing is compressed between the fully extended pumping finger and the door platen, thus preventing free flow. The pumping mechanism is activated following actuation of the START control in conjunction with normal instrument operating procedures. The stepper motor rotates the camshaft at a cyclical rate proportional to the programmed infusion rate. Each pumping cycle consist of 200 motor steps of 1.8° each. Inter-step timing of the motor is varied as necessary to dampen the inherent non-linearity of peristaltic pumping mechanisms and produce a uniform rate of fluid flow across each pumping cycle. The sequential extension and retraction of the pumping fingers from top to bottom results in a downward moving compression zone within the administration set's pumping segment (see Figure 4-1) which creates positive pressure on the outlet side (distal end) of the tubing set. The elastomeric resilience of the pumping segment tubing causes it to return to its cylindrical shape as each of the pumping fingers recede from the extended position. This reshaping creates a vacuum in the proximal tubing and causes fluid from the IV solution container to refill the tubing. This peristaltic like action results in a constant, controlled flow of IV solution from the bottle to the patient. During the pumping cycle, between motor steps 62 through 77, the strain beam senses the hydrostatic pressure in the column of fluid above the strain beam. In the event there is restricted flow in the tubing set between the bottle and the pump and the tubing can not refill completely, the strain beam will sense a lower than normal pressure and cause the pump/controller to enter either a LOW FLOW condition when operating in the Controller mode or either a PARTIAL OCCLUSION-FLUID SIDE or OCCLUSION-FLUID SIDE condition when in the Pump mode.

In the Controller mode if the pressure differential between patient and bottle drops to less than 6 inches of water pressure (0.25 psi), the pumping mechanism will stop. The microprocessor monitors the duration of a 'low flow' condition, automatically increases the programmed delivery rate by ten percent and resumes pumping once the bottle to patient pressure differential exceeds 12 inches of water pressure. The increased flow rate allows the instrument to compensate for the period of 'low flow' and bring the actual volume infused in line with the programmed infusion parameters. Once the pump has completed this catch-up cycle, the delivery rate reverts to the programmed rate. Should the 'low flow' condition persist for more than 1 minute or the calculated time necessary to compensate for the under-infusion condition exceeds 30 minutes, the instrument will enter an Occlusion alarm condition.

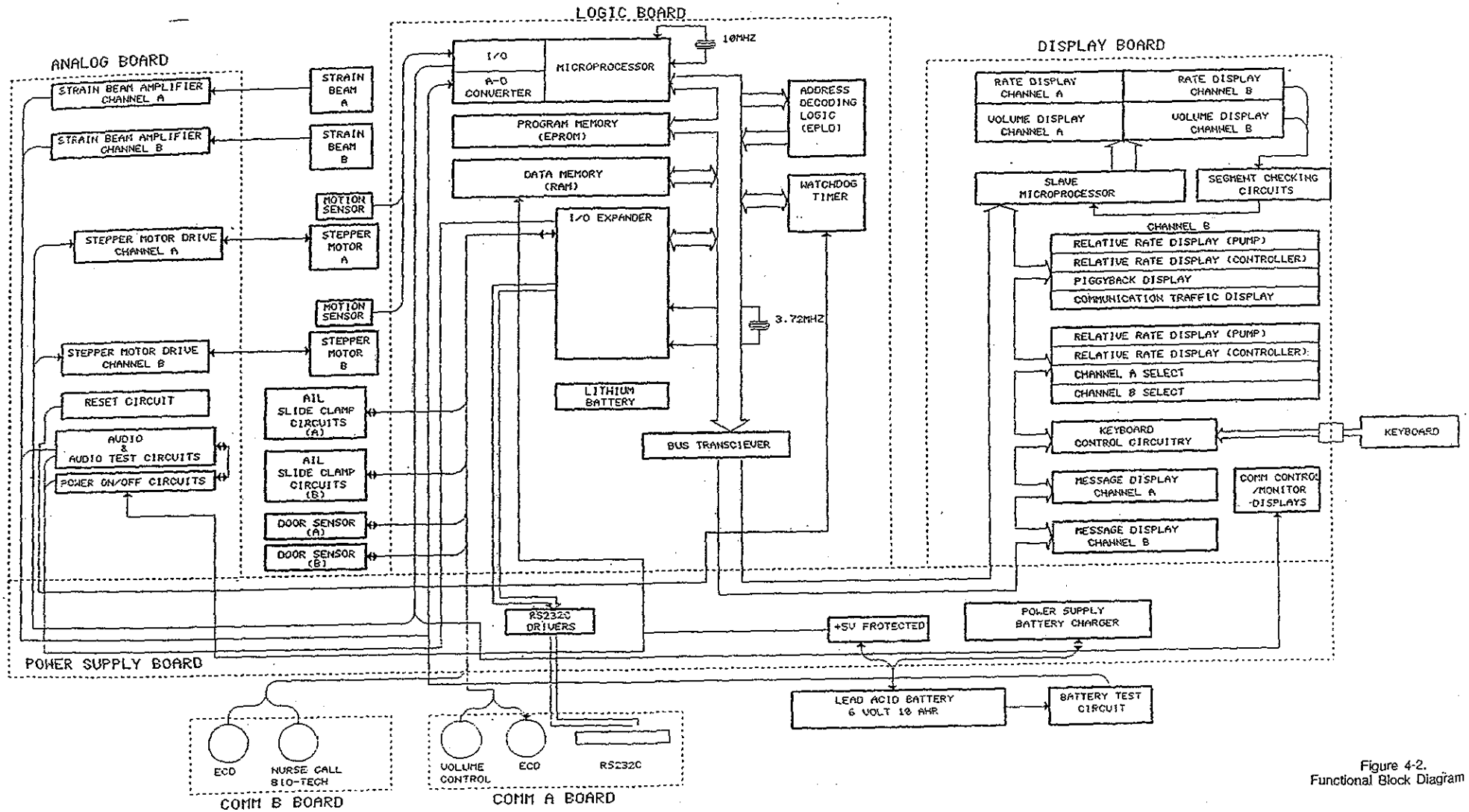


Figure 4-2.
Functional Block Diagram

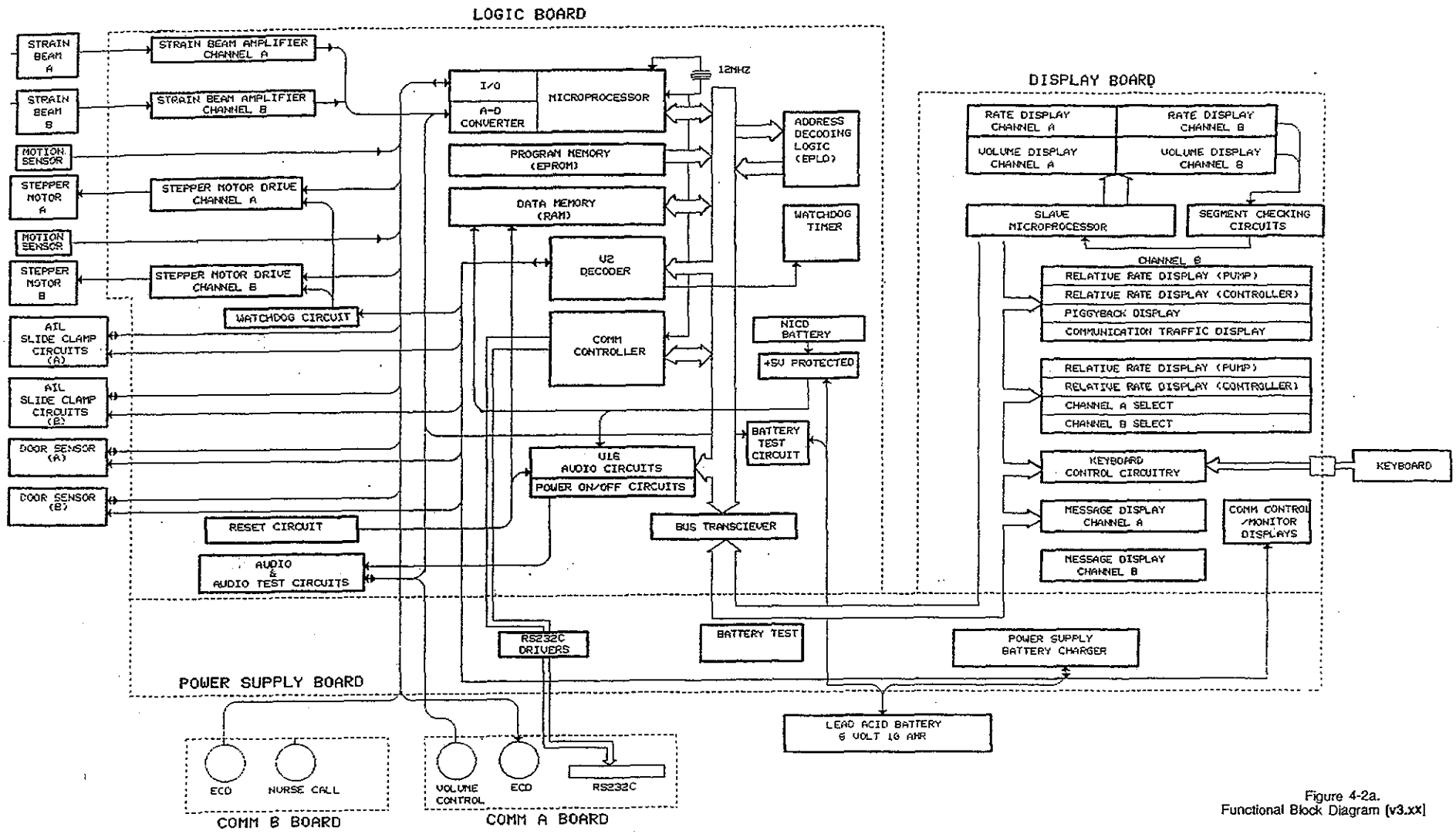


Figure 4-2a.
Functional Block Diagram (v3.xx)

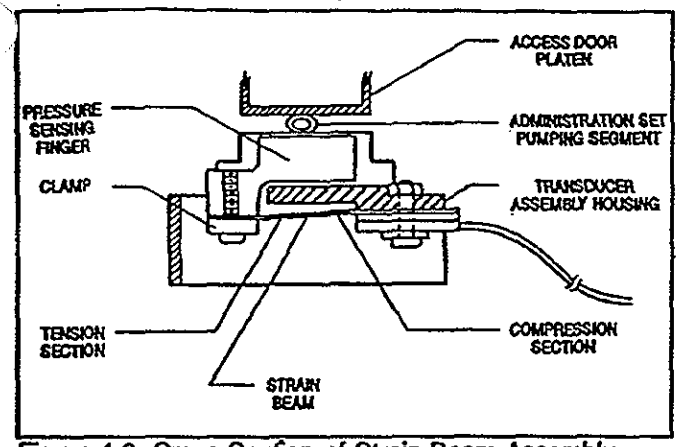


Figure 4-3. Cross Section of Strain Beam Assembly

During a pumping cycle, between motor steps 0 through 20 and 120 through 199, the strain beam measures the pressure in the distal tubing. Any restriction to flow in the distal tubing will cause the pressure to increase and the tubing to expand. The strain beam will sense this increasing pressure and when it exceeds a predetermined value will cause the pump/controller to invoke either an OCCLUSION (Controller mode) or an OCCLUSION-PATIENT SIDE (Pump mode) alarm condition. During any alarm condition, the pumping mechanism stops and appropriate audio and visual alerts are issued. (Between motor steps 21-62 and 77-119 the pressure sensor can not read distal or proximal pressure).

4.2.2.2 Strain Beam (Pressure Transducer)

When the pumping segment of a primed administration set is installed in a PC-2 pumping chamber and the access door is closed, the strain beam will sense the pressure in the tubing. Actual pressure values are determined by pumping finger position within a pumping cycle and the hydrostatic pressure in the tubing at the time of measurement. A typical strain beam voltage would be in the range of 1 to 3 volts if the strain beam was looking at the patient. During pump operation a positive pressure increase in the fluid column above or below the pump will cause the tubing to expand and result in deflection of the strain beam. This deflection will result in an increase in the potential measured across the bridge. A decrease in pressure within the tubing set's fluid column will result in contraction of the tubing diameter with a resultant deflection of the strain beam and a reduction in the potential measured across the bridge circuit.

4.3 ELECTRICAL/ELECTRONIC OPERATION

An understanding of the electrical/electronic theory of operation can be acquired by reading the ensuing subsystem descriptions while following the functional schematic for the respective subsystem.

4.3.1 Functional Description

Integer Keypad/Series v2.xx Software

The PC-2's electrical/electronic subsystem is operated and controlled by a logic subsystem employing an Intel 8097-90 16 bit microcontroller with an integral A/D converter. The logic subsystem includes a programmed memory containing the instrument's operating code; a non-volatile memory for retention of infusion parameters input through the user interface, error log storage and general system use; a watchdog timer circuit to conduct sanity checks on the processor and monitor hardware performance; a logic decoder to define memory space, implement ready logic and decode data strobes; an I/O expander to handle the serial port and parallel logic ports; a keypad logic interface and a display logic interface. The interaction of the logic subsystem components and instrument hardware is functionally depicted in the Logic Block diagram, Figure 4-2. The electrical interconnection of the instrument's components is shown in Figure 4-5.

The memory accessible by the main processor covers 64K bytes of combined internal RAM and register space which is allocated as follows: 256 bytes to internal microprocessor RAM, 3840 bytes to mapped I/O, 4096 bytes to external RAM (Variable, Stack and NVRAM memory) and 56K bytes to external ROM (Program and Data Memory).

A 10 MHz crystal external to the microcontroller provides the master clock signal. The time base is monitored by an independent 3.072 MHz oscillator that is synchronized with the crystal. A timing discrepancy >1.5% is treated as a timebase failure and will result in immediate instrument shutdown. The microprocessor timing waveforms are shown in Figure 4-4.

The watchdog timer (U4) provides a failsafe feature to monitor hardware performance during instrument operation. In the event the microprocessor departs from its normal timing sequence or attempts to execute erroneous instructions, the watchdog timer will timeout and the instrument will enter watchdog alarm.

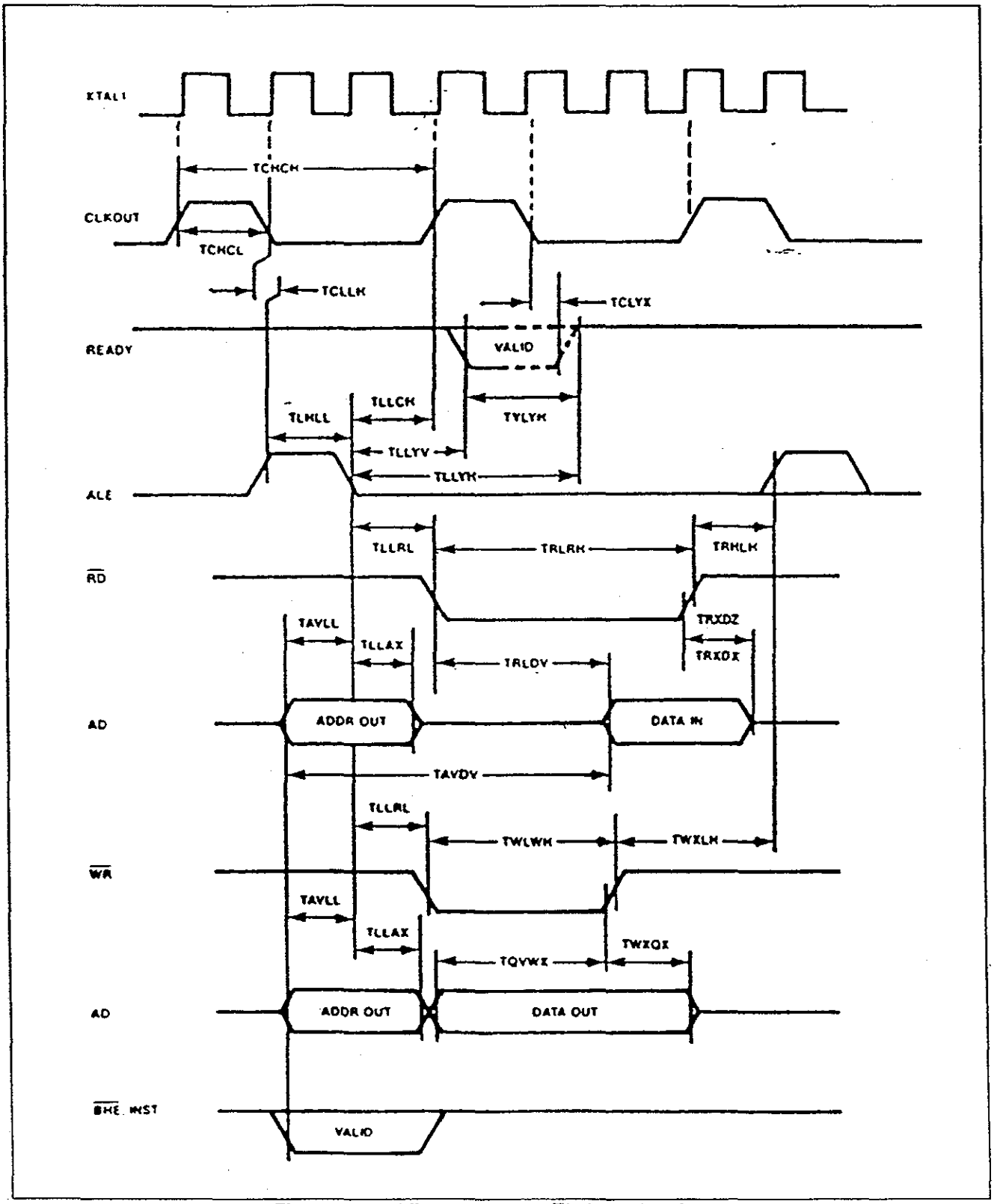


Figure 4-4. Microprocessor Timing Waveforms

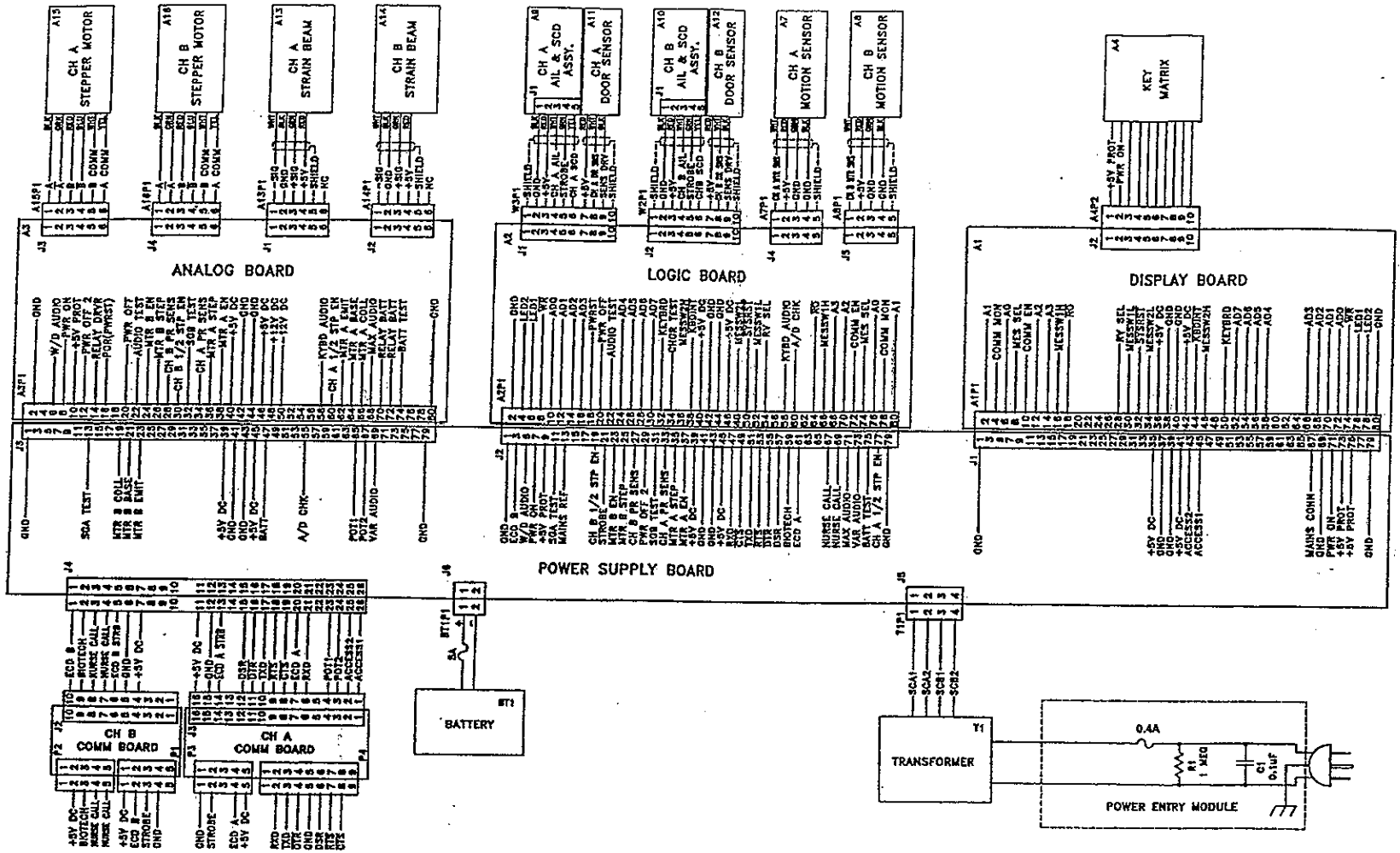


Figure 4-5. PC-2 Electrical Interconnect Diagram

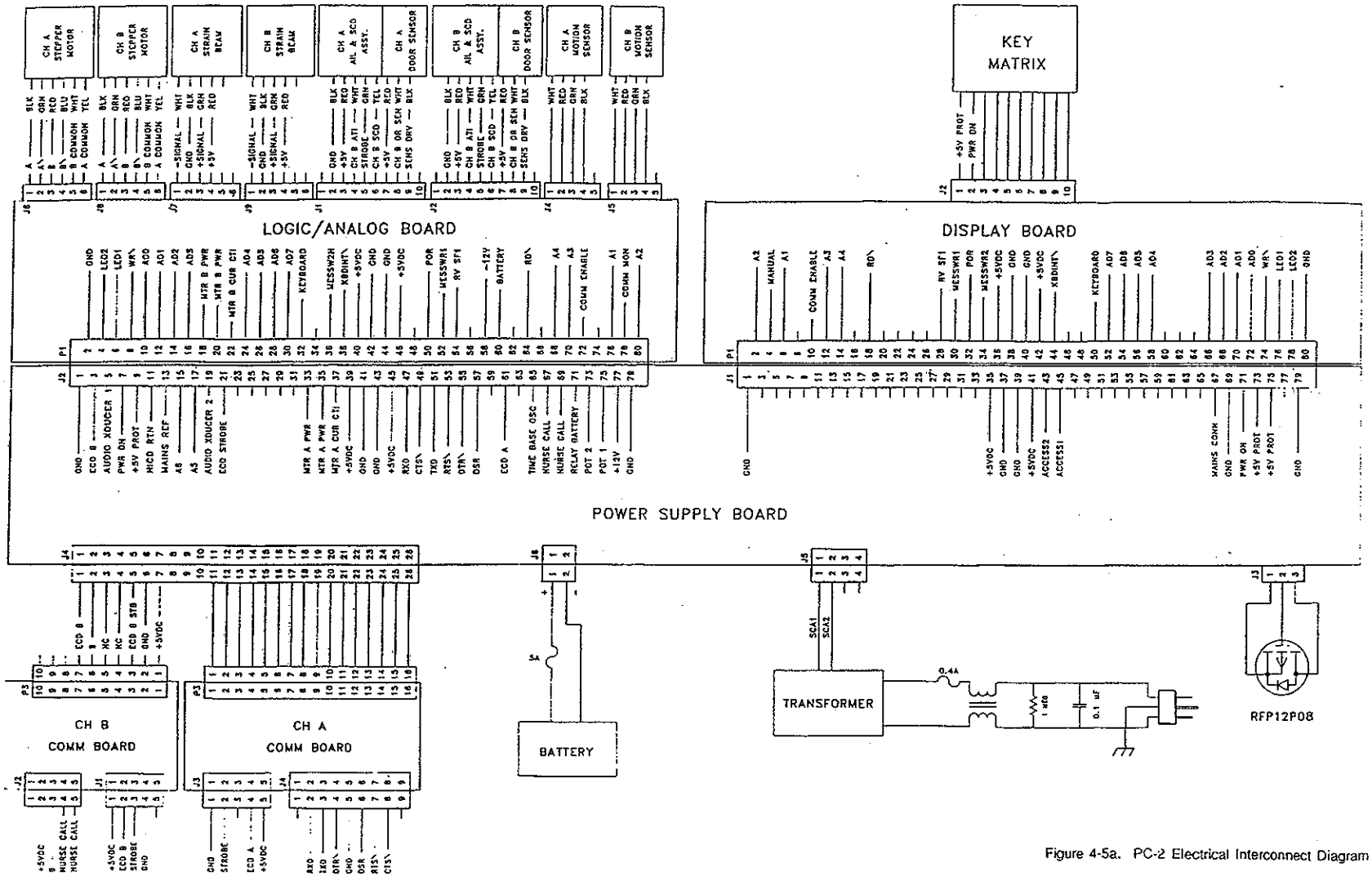


Figure 4-5a. PC-2 Electrical Interconnect Diagram (v.3xx)

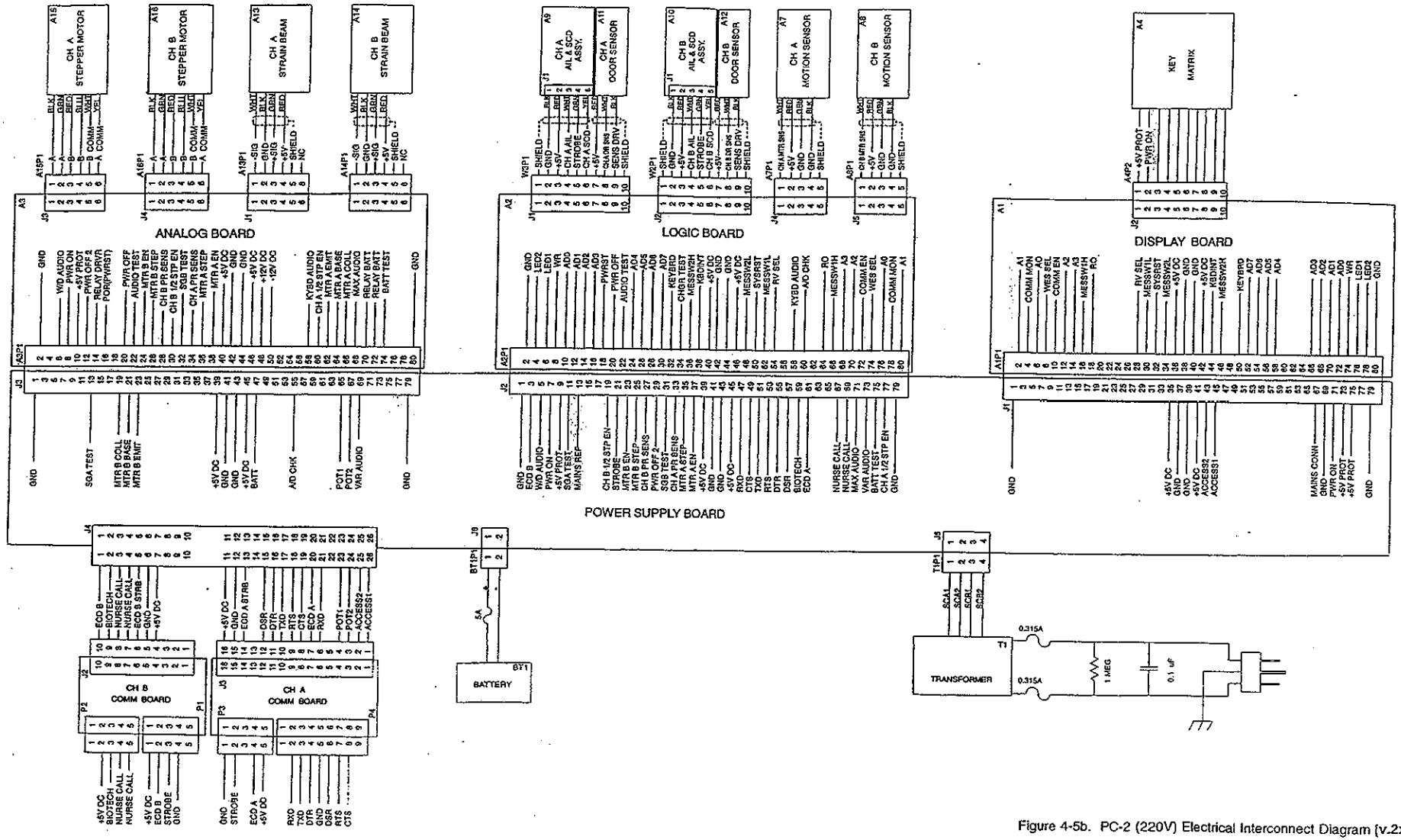


Figure 4-5b. PC-2 (220V) Electrical Interconnect Diagram [v.2xx]

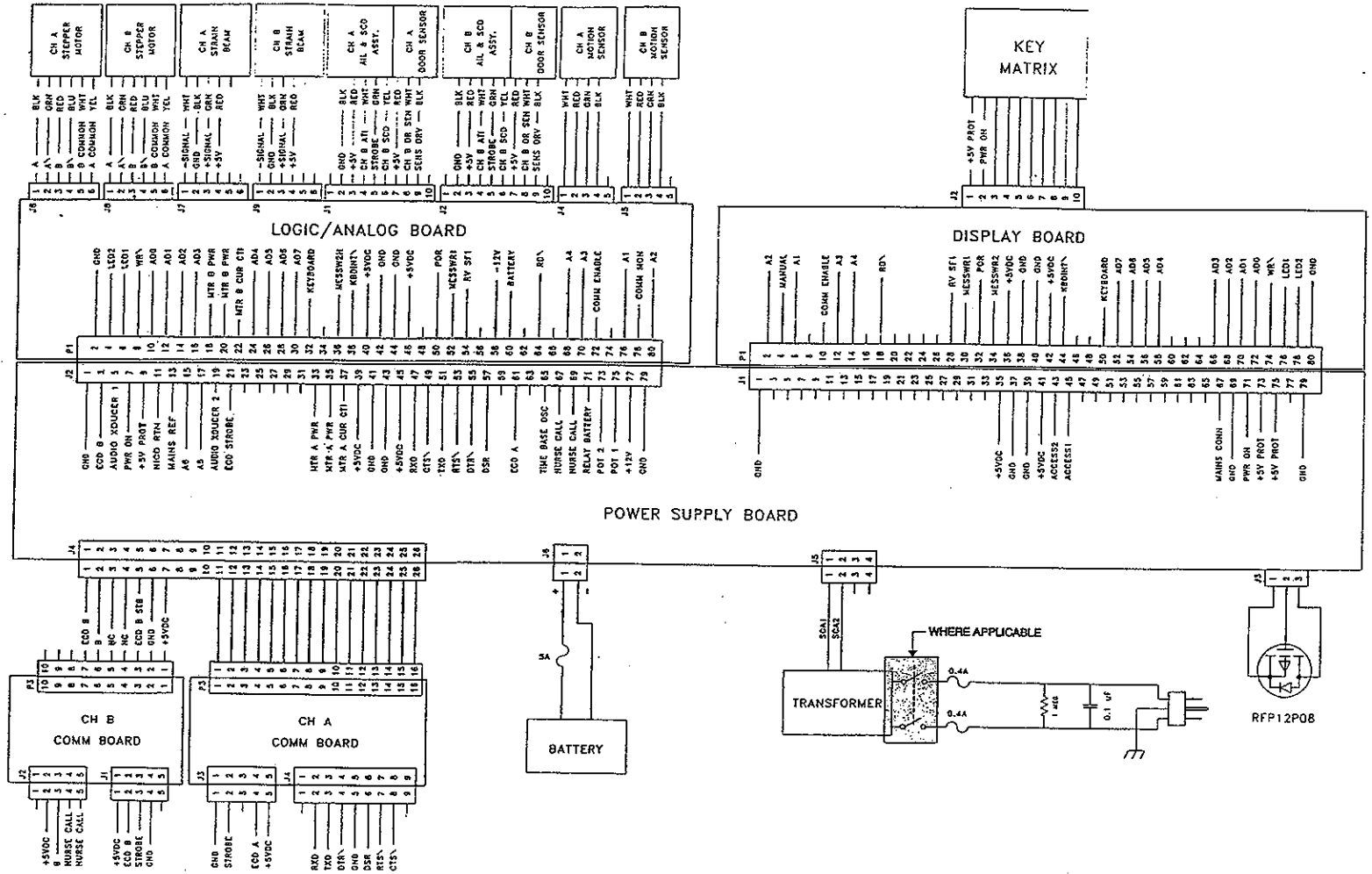
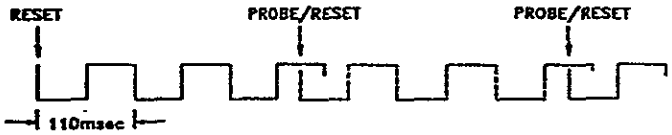


Figure 4-5c. PC-2 (220V) Electrical Interconnect Diagram [v3.xx]

Approximately 55 msec after a watchdog reset, the timer outputs a high signal with a 110 msec period and a 50% duty cycle (see diagram at end of paragraph). Upon completion of an instruction string, every 300 msec, the processor probes the watchdog. Under normal conditions the probe will query the watchdog timer during the third high following reset and then reset the timer. If the probe fails to query the timer within 1.2 seconds (timeout) or queries the timer during a low the instrument will enter watchdog alarm.



Fractional Keypad/Series v3.xx Software
The PC-2's electrical/electronic subsystem is operated and controlled by a logic subsystem employing an Intel 80C196KB 16 bit microcontroller with an integral A/D converter. The logic subsystem includes a programmed memory containing the instrument's operating code; a non-volatile memory for retention of infusion parameters input through the user interface, error log storage and general system use; a watchdog timer circuit to conduct sanity checks on the processor and monitor hardware performance; a logic decoder to define memory space, implement ready logic and decode data strobes; a communications contorller to handle the serial port ; a keypad logic interface and a display logic interface. The interaction of the logic subsystem components and instrument hardware is functionally depicted in the Logic Block diagram, Figure 4-2a. The electrical interconnection of the instrument's components is shown in Figure 4-5.

The 80C196KB's architecture utilizies a linear non-segmented 64K bit address space. This means that ram, rom and IO share this space which is organized as 32K 16 bit words. The program memory resides in 256K bytes of EPROM organized as 4 banks of 32K 16 bit words, data memory resides in two 8K byte static rams organized as 8K 16 bit words and I/O is implement in the custom ic's U2 and U16. U2 also implements the address decoding and data strobes for the display interface. Since the processor is capable of addressing only 64K bytes, ROM bank switching is used.

A 12 MHz crystal external to the microcontroller provides the master clock signal. A second clock signal is generated on the display board by the 8742 slave controller and is used to clock timer T2 on the 80C196KB U1 pin 44. The count in T2 is compared with timer T1 in the 80C196KB by software. A timing discrepancy >1.5% is treated as a timebase failure and will result in immediate generation of an internal error. The microprocessor timing waveforms are shown in Figure 4-4.

The watchdog timer comprised of Q9 and associated gate bias circuits provide a failsafe feature to monitor hardware performance during instrument operation. In the event the microprocessor departs from its normal timing sequence or attempts to execute erroneous instructions, the watchdog timer will timeout and the instrument will enter watchdog alarm.

A pulse train is generated by the 80C196KB through the EPLD U2 pin 9 which is AC coupled through C79 and rectified by CR28 and CR29 providing the gate bias for Q9. Q9, under normal operating conditions, is biased on. The drain of Q9 is connected to the non-inverting input of U23 and U28 through diodes CR27 and CR26 and pulled up to 5V by RA2 pin 10. In the event of a watchdog condition Q9 is biased off allowing RA2 to pull up the inputs of U23 and U28 thus removing power to the motors. The drain is also connected to the custom ic U16 pin 22 which when driven high by the watchdog condition will generate a max audio.

4.3.2 Functional Operation

4.3.2.1 Power On/Power Off Subsystem

Integer Keypad/Series v2.xx Software
The Power On circuitry is distributed onto the Analog and Power Supply Boards and includes an interface through the Display Board to the Keypad (see Figure 4-6). The Analog board contains the power on logic circuit and the battery relay circuit is on the Power Supply board.

With the instrument in the power-off condition U10 pins 1 & 2 are high producing a low to U13 thereby applying a high to U8 pin 9. The latch is held enabled which results in a high from U8 pin 15 to U11 pin 10. The output of U7 pin 6 to U10 pin 2 and U11 pin 11 is also high.

Actuating the POWER ON switch supplies a high to U11 pin 9 which allows U11 pin 8 to output a

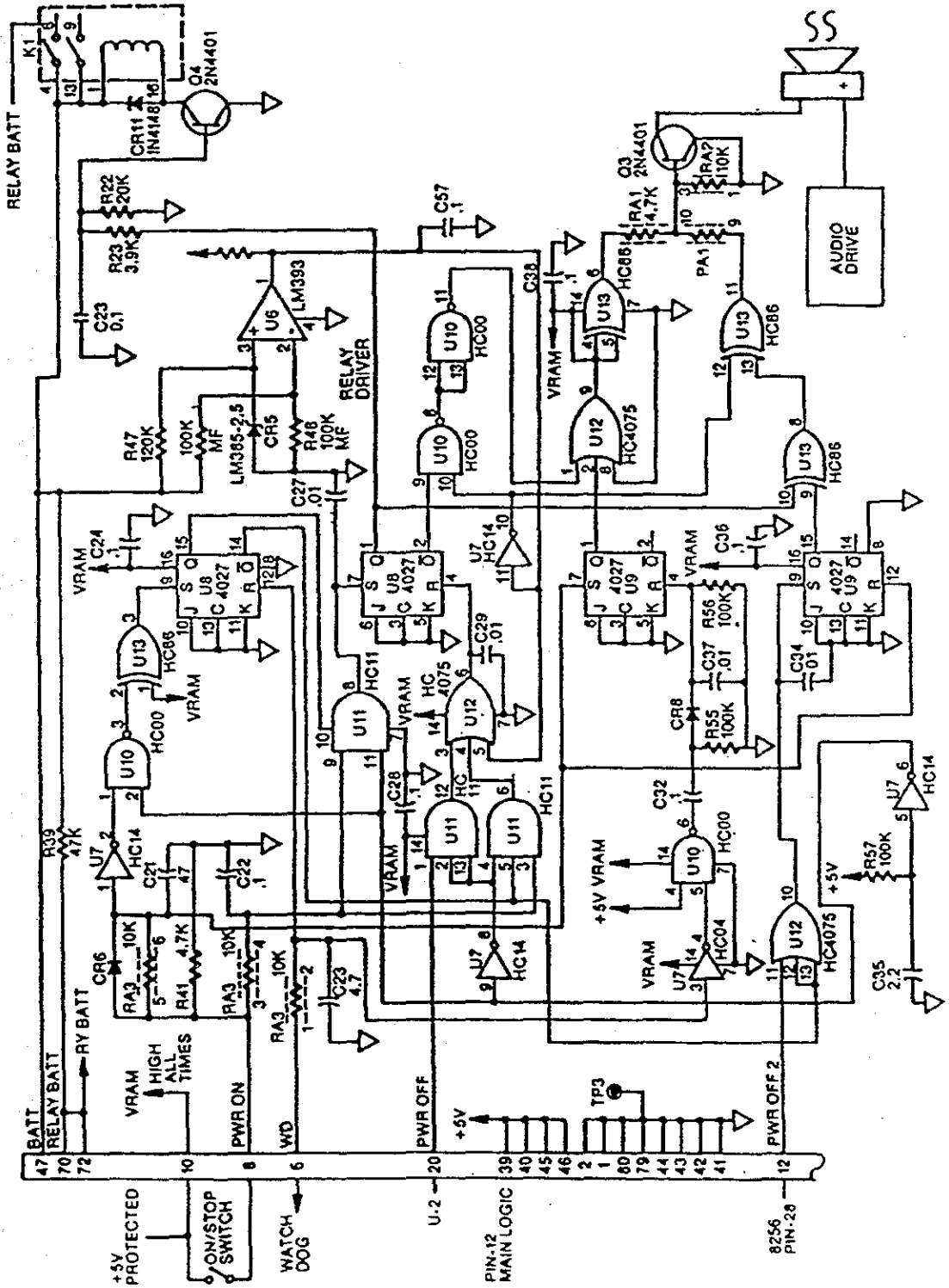


Figure 4-6. Power On/Power Off Subsystem - Functional Schematic [v2.xx]

high to U8, pin 7 setting the latch. U8, pin #1 outputs a high to the base of Q4 turning on the transistor, energizing the K1 relay coil and closing the relay.

Following a 200 msec timing delay, the output of U7 pin 6 goes low, disabling the Power On signal U10 pin 1 and U11 pin 9; the Power Off signal at U11 pin 1 and enables the watchdog power off path through U11 pins 3 and 5.

The Power Off function can occur in one of three scenarios: Normal (software initiated), Watchdog and Low Battery.

During a normal shut down, the microprocessor changes the Power Off 2 line from a low to a high and then inputs a high through U2 to U11 pin 1, which outputs a high through U12 to U8 pin 4 which clears the latch. U8 pin 1 goes low, Q4 is turned off and the K1 coil is de-energized and the battery relay opens. If the processor fails to set Power Off 2 high malfunction audio will sound to indicate improper shut down.

In the event of a Watchdog malfunction the microprocessor sends a high to the audio circuit to activate the malfunction audio alarm. This also sends a high to U8 pin 12 clearing the latch. The output of U8 pin 14 is high to U11 pin 5; thereby enabling the POWER ON switch to shut down the instrument.

If a Low Battery III condition occurs, a high is input directly to U12 pin 5 which puts out a high to U8 pin 4 which resets the latch and turns the power off.

Fractional Keypad/Series v3.xx Software

The Power On circuitry is distributed onto the logic and Power Supply Boards and includes an interface through the Display Board to the Keypad. The logic board (Figure 4-29, sheet 2, grid D8) contains the power on logic circuit in the EPLD U16 with the output, pin 19, driving the battery relay circuit on the Power Supply board (Figure 4-27, sheet 1, grid D7/8).

Actuating the POWER ON switch supplies a high to U16 pin 16 which allows U16 pin 19 to output a high to the base of Q7 turning on the transistor, energizing the K1 relay coil and closing the relay on the power supply board.

Following a 200 msec timing delay, the input to U16 pin 2 goes high disabling the power on function of the POWER ON switch. In the event of a watchdog event the POWER ON key will be enabled by the watchdog signal on U16 pin 22 to power off the instrument.

The Power Off function can occur in one of three scenarios: Normal (software initiated), Watchdog and Low Battery.

During a normal shut down, the microprocessor changes the Power Off 2 line from a low to a high, U16 pin 23. The sofware then writes to two consecutive addresses. The first address enables the input to the power on latch in U16 and the second address resets the latch causing U16 pin 19 to go low thus removing the drive to Q7. Q7 is turned off and the K1 coil is de-energized and the battery relay opens. If the processor fails to set Power Off 2 high malfunction audio will sound to indicate improper shut down.

In the event of a Watchdog malfunction the input to U16 pin 22 enables the POWER ON switch for the power off function and generates a max audio on U16 pin 18.

If a Low Battery III condition occurs, a high is input directly to U12 pin 7 which puts out a high to U16 pin 20 which resets the latch and turns the power off and generates a max audio, U16 pin 18 goes high. The POWER ON key becomes active as an audio disable function.

4.3.2.2 5 Volt Regulator Subsystem

Integer Keypad/Series v2.xx Software

When the K1 battery relay is energized (see Figure 4-6), the linear 5V regulator is active and provides 5VDC to the instrument electronics. This regulator consists of a UC3834 linear voltage regulator and a PNP pass transistor (Q5). The regulator also provides over current limit protection of ≈3 Amps by comparing the voltage drop across R24, R25 and R26 against an internal voltage reference. The switched battery output from relay K1 is also used to provide scaled battery voltage input to the system A/D converter for low battery voltage detection. The scaled battery voltage is provided by a resistor voltage divider with a ratio of 2 ±1%

The 5VDC protected voltage is provided by the system battery through the LM2931 low voltage drop regulator. This regulator is capable of providing in excess of 50mA with a dropout voltage of <0.3 volts. The no-load biasing current is <1 mA which is important as the driver is always connected to the system battery.

Fractional Keypad/Series v3.xx Software

The 5 volt power supply regulates the switched battery voltage (see Figure 4-27 Sheet 1, Grid C7 to F10) from relay K1. Op amp U4 compares the voltage at U4-3 with the precision 2.5 Volt reference at U4-2 established by D14. When these two voltages are not equal, the output at U4-1 to the gate of the external p- channel FET is adjusted to equalize the voltages at U4-2,-3. Since the output voltage from the FET is divided by two (via R17 and R26), the resultant output voltage will be 5 VDC when U4-2, -3 are equal.

5 Volt system current monitoring is accomplished by comparing the voltage drop across R28 with a fixed 0.15 VDC formed by divider R30, R31. If the voltage across R28 ever exceeds 0.15 Volts (3 amps), the output of U4-7 goes high forcing U4-3 above the 2.5 Volt reference and turns off the external FET.

The 5 volt output is divided down by R24 and R39 and compared by U9-5 and -6 with another 2.5 Volt reference (D15). If the 5 volt output ever exceeds 5.45 VDC, the output of U9-7 is set low turning off relay K1 via Q7. The instrument will thus power down (with an audible alarm) if the 5 volt power supply is defective.

4.3.2.3 ±12 Volt DC Power Supply Subsystem

Integer Keypad/Series v2.xx Software

The ±12 volt DC power supply subsystem is incorporated into the Analog Board and consists of transformer T1, an oscillator circuit on the primary windings and a rectifier circuit on the secondary windings. The functional schematic of the 12 volt power supply is shown in Figure 4-7. +5VDC is supplied to the center tap of the primary windings which induces a current to activate the base of one of the transistors. This allows current to flow through the primary windings until the transformer is saturated. Once saturated the base of the active transistor shuts off and the other transistor activates. This produces a reversal in the direction of current flow through the primary windings, increases the magnetic flux to saturation followed by a switching of the active transistor. This oscillation induces 12 volt AC in the secondary windings which is rectified by the diode bridge and emerges as unregulated ±12 volts DC.

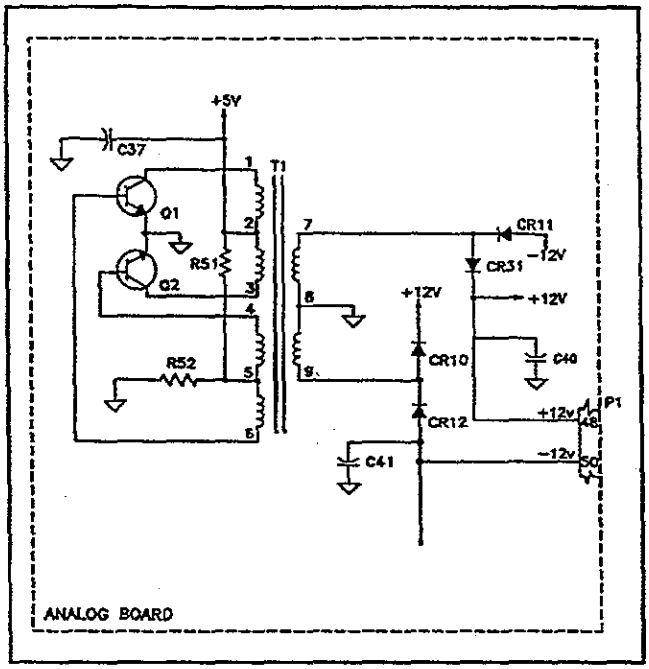


Figure 4-7. 12V Power Supply Functional Schematic [v2.xx]

Fractional Keypad/Series v3.xx Software

The ±12 volt DC power supply subsystem is incorporated into the logic board (Fig 4-29, Sheet 2 Grid E1 to E5) and is implemented with a LM3578 switching regulator. Battery is supplied to transformer (T1) at pin 2. Pin 5 of the transformer primary winding is routed to regulator U11 pin 6 the collector of the internal pass element. When the transistor is turned on, energy is stored in the primary of T3 until U11 turns off the transistor. The voltage induced in the transformer's secondary is blocked by diodes CR1 and CR2. When the transistor is turned off. the current in the transformer primary in maintained by the collapsing magnetic field inducing current in the transformer secondary which forward biases diodes CR1 and CR2 charging capacitors C17 and C18. The charged capacitors provide +12 and -12 volt outputs. These outputs are monitored by R23 and R24 respectively and are fed back into the chip-resident comparitor which adjusts the duty cycle of the transistor to maintain a 24 volt differential across the transformer output terminals.

4.3.2.4 Battery Charger Subsystem

Integer Keypad/Series v2.xx Software

The battery charger subsystem consists of the AC power input module, the transformer and the battery charger logic circuitry. The power input module and transformer are attached to the rear case and the logic circuitry is incorporated into the

Power Supply Board (see Figure 4-8). AC power is supplied to the dual wound step down transformer through an EMI filter and protective fuse. The dual primary windings enable use of the transformer with both 120 or 240 VAC sources. The dual secondary windings output 14.6 V_{RMS} for battery charging and 8.5 V_{RMS} for regulating the charger Both secondary outputs are rectified and filtered for use in the switching battery charger. Schottkey diodes are used to rectify the 14.6 V_{RMS} to minimize power loss; the 8.5 V_{RMS} output is rectified using conventional diodes as current requirements are minimal. The battery charger uses a switching regulator to minimize power dissipation. A PNP pass transistor (Q1) is switched at ≈22KHz to prevent the generation of audible noise. The pulse width, or duty cycle, is controlled by a UC2524 Pulse Width Modulated (PWM) controller. The controller sets the pulse width to limit the voltage to 6.9 ±0.1 volts. The output of the pass transistor passes through a conventional LC filter which removes the AC component from the PWM output. The battery over-voltage protection circuit, consisting of transistors Q2 and Q3 with their interconnecting resistors, limit the applied charging voltage to 8V maximum. The comparator circuit consisting of R17, R20 and R21 and op-amp U2 limit charging current to 2.7A.

The battery charger also provides a source of current to illuminate the Mains Connected LED as well as providing a nominal 2.5V source to the A/D converter which indicates to the processor that the mains are connected.

Fractional Keypad/Series v3.xx Software
The battery charger consists of components mounted on the power supply board. The circuit utilizes a switching regulator concept (Figure 4-27, sheet 1, grid C1 to E7) based on the UC2524A (U3) regulator chip. Unregulated AC voltage is rectified through the diode bridge (D3, D5, D7, D8). The unregulated DC output from the rectifier bridge charges capacitor C10. C10 provides filtered DC voltage to the regulator chip and the switching circuit consisting of Q1, Q10, and Q4.

Battery charger output is reduced by the resistor divider consisting of R54, R20 and R16 and then applied to U3-1. U3 compares this voltage against a 5 volt reference voltage at U3-2 and adjusts the duty cycle of U3-12 and U3-13, when these two voltages are unequal. This variable duty cycle is level shifted through Q1 and Q10 and applied to the gate of FET Q4. This results in Q4 having a duty cycle equal to that on U3-12/13. The voltage input to L1 is approximately a 20 volts p-p square wave at a switching frequency of ≈25KHz. The AC component is filtered out by the L1/C5 low pass filter and is applied to the battery.

Charger output is monitored by a circuit consisting of U11, D17 R55 and R56. When the battery voltage exceeds ≈7.8 Volts, the voltage at the divider consisting of R55 and R56 exceeds the reference voltage of D17 (2.5VDC). When this occurs the output of U11 switches to a positive voltage thus turning on transistor Q12 which turns on Q11. Turning on Q11 turns off the drive to Q1, Q10 and thus Q4. This has the effect of turning the charger completely off while the battery voltage exceeds 7.8VDC.

Battery current is monitored by U3 and limited to ≈3 amps by adjusting the duty cycle of FET Q4 as discussed above. Battery current is sensed by R51 and applied differentially to U3-5 and U3-4. When this voltage exceeds 0.2VDC, U3 reduces the duty cycle to yield a current limit of ≈3 amps.

Battery voltage is adjusted by R54 to produce an output voltage of 6.9 VDC when the battery current is below ≈500 ma. Battery current is monitored by another amplifier in U11 via the voltage drop across R5. When the battery current exceeds ≈500 ma, the output of U11 switches low thus connecting R27 in parallel with R16. This has the effect of increasing the charger output voltage to 7.4 VDC. This dual state charging feature allows rapid and complete charging of the battery when needed and then switch back to the 6.9 VDC level as a float level to prolong battery life.

4.3.2.5 System Reset Circuit

Integer Keypad/Series v2.xx Software
The system reset circuit shown in Figure 4-9 protects the NVRAM during Power On and Power Off cycles. With the battery relay open the output at U6 pin 7 is low. When the relay battery is applied U6 pin 7 goes high after the time constant delay established by R39, R44 and C26. This signal is OR gated with the Watchdog reset in U10 which generates a system reset at U10 Pin 21. This initiates the 8097 micro-processor and the 8256 I/O controller on the logic board and the display board. The power on reset U6 pin 7 is also gated with the NVRAM chip select in U16. When U16 pin 5 goes high, the system processor and memory are enabled and operation begins. This circuit disables the

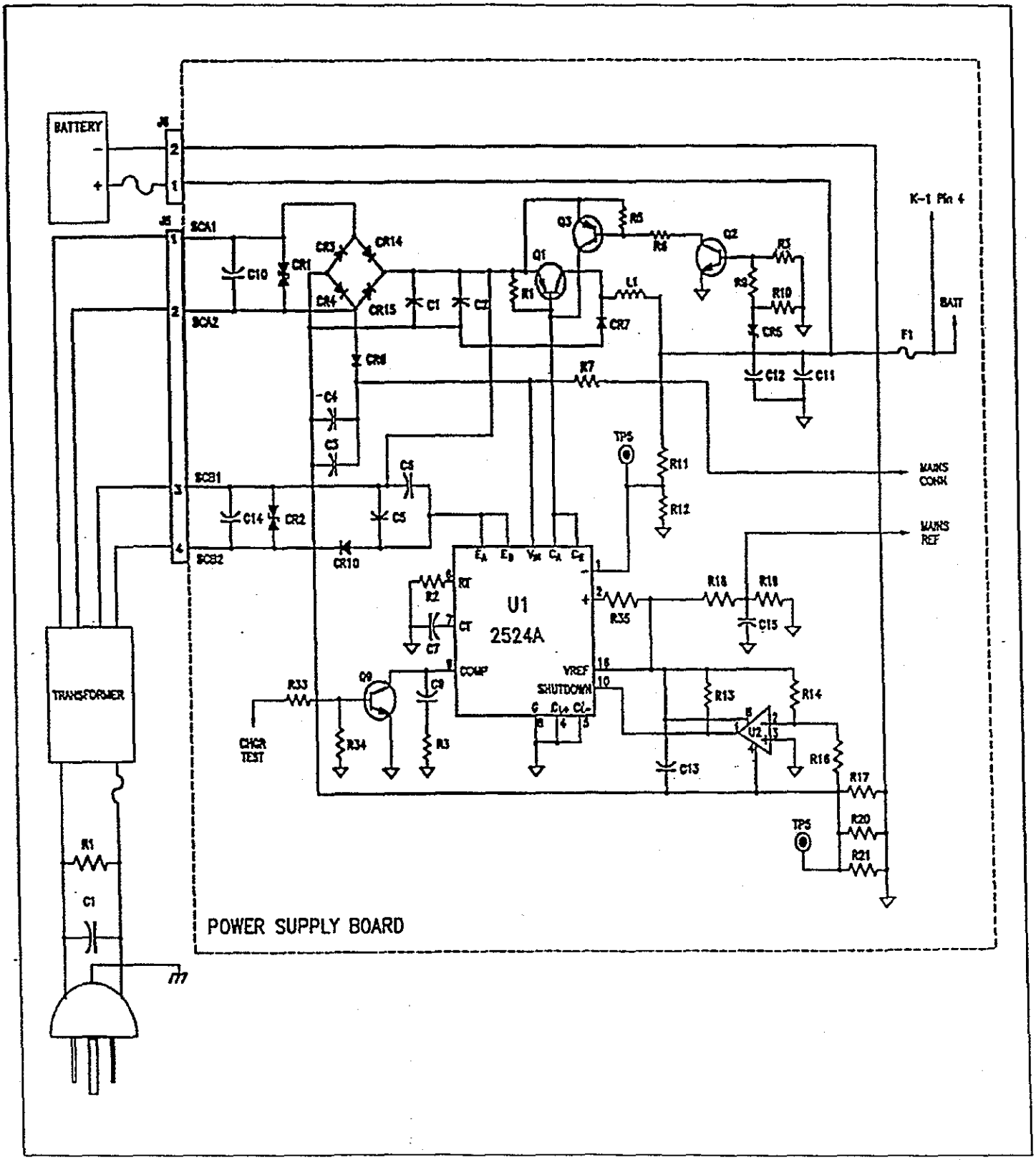


Figure 4-8. Battery Charger Functional Schematic (Integer Keypad/Series v2.xx Software)

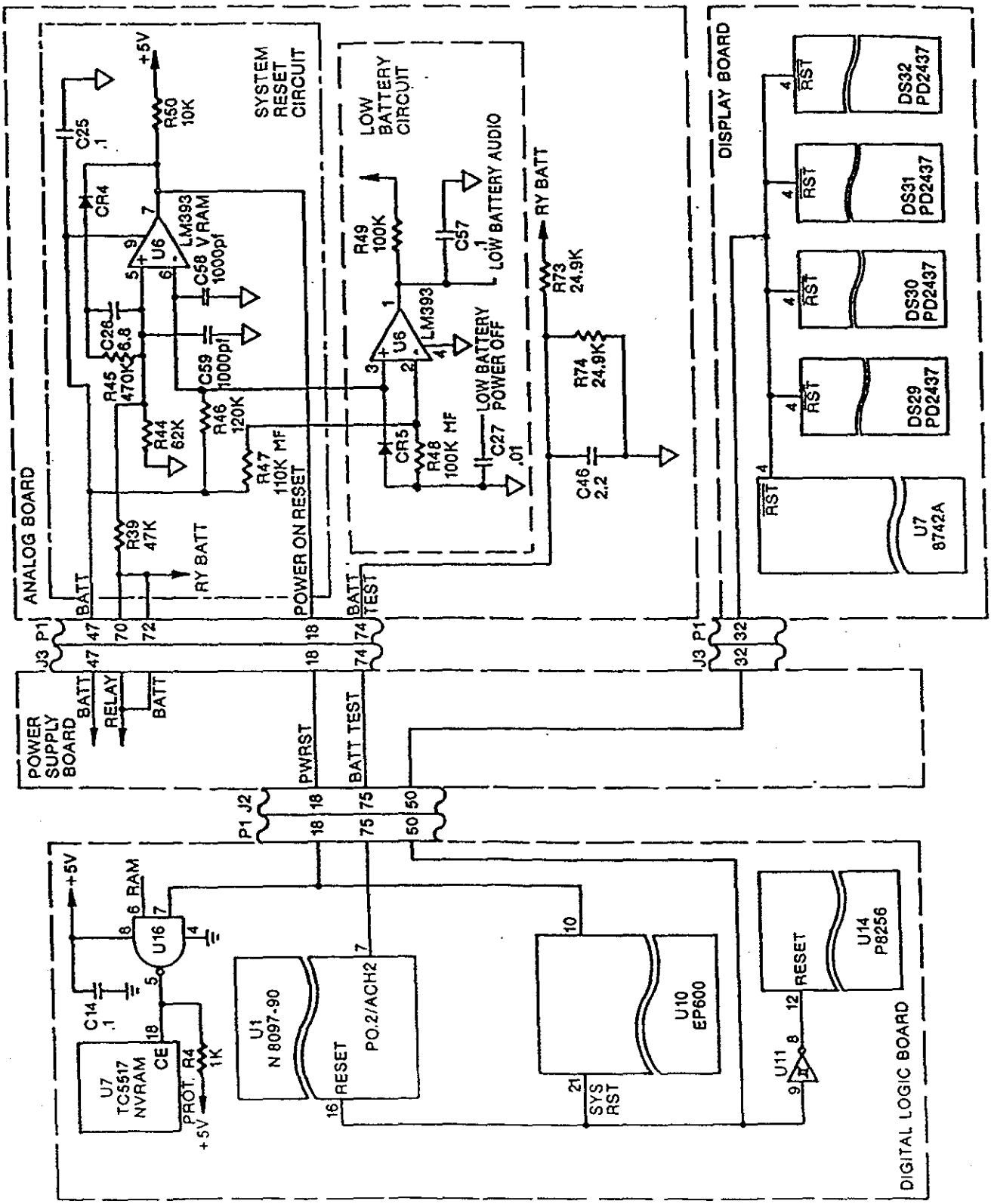


Figure 4-9. System Reset/Low Battery Detection Subsystem - Functional Schematic [v2.xx]

processor while system voltages are unstable during power up and power down.

4.3.2.6 Battery Depleted Circuit

Integer Keypad/Series v2.xx Software
The Low Battery detection subsystem consists of a comparator circuit and the Op-amp U6 (see Figure 4-9). A voltage threshold is established by R47 and R48. When battery voltage crosses the threshold the Op-amp output changes from a low to a high and a power down signal is sent to U12 pin 5. U12 pin 6 goes high and U8 latch is reset which powers down the instrument.

Fractional Keypad/Series v3.xx Software
The system reset circuit shown in Figure 4-29, sheet 2, grid E7, protects the NVRAM during Power On and Power Off cycles. With the battery relay open the output at U12 pin 1 is low. When the relay battery is applied U12 pin 1 goes high after the time constant delay established by R35, R91 and C28. This initiates the 80C196KB microprocessor, the 82050 serial controller, the logic in the custom ics U2, U16 on the logic board, as well as the slave microprocessor and the dot matrix displays on the display board. The power on reset U12 pin 1 is also connected to the NVRAM chip select pin 26 of U7 and U8. This circuit disables the processor from accessing the ram while system voltages are unstable during power up and power down.

4.3.2.7 Pumping Mechanism

The pumping mechanism employs a hybrid stepper motor to provide the torque to turn the camshaft and operate the pumping fingers. A microprocessor based motor control circuit (see Figure 4-10) is used to generate the motor operating pulses. The hybrid motor employs a multi-toothed rotor and stator with an axially magnetized concentric magnet mounted on the rotor shaft. The teeth on the iron cups attached to the opposite ends of the concentric, permanent magnet are offset from each other one half tooth pitch. The rotor to stator tooth ratio is 50:48. This provides 7.5° stator and 7.2° rotor inter-tooth spacing. The 0.3° differential across a six stator tooth span (45° of arc) provides a 1.8° rotor to stator offset. The stator is wound in a four-pole four-phase configuration. Stator polarity changes 45° as each of the four phases is sequentially energized (see following diagram).

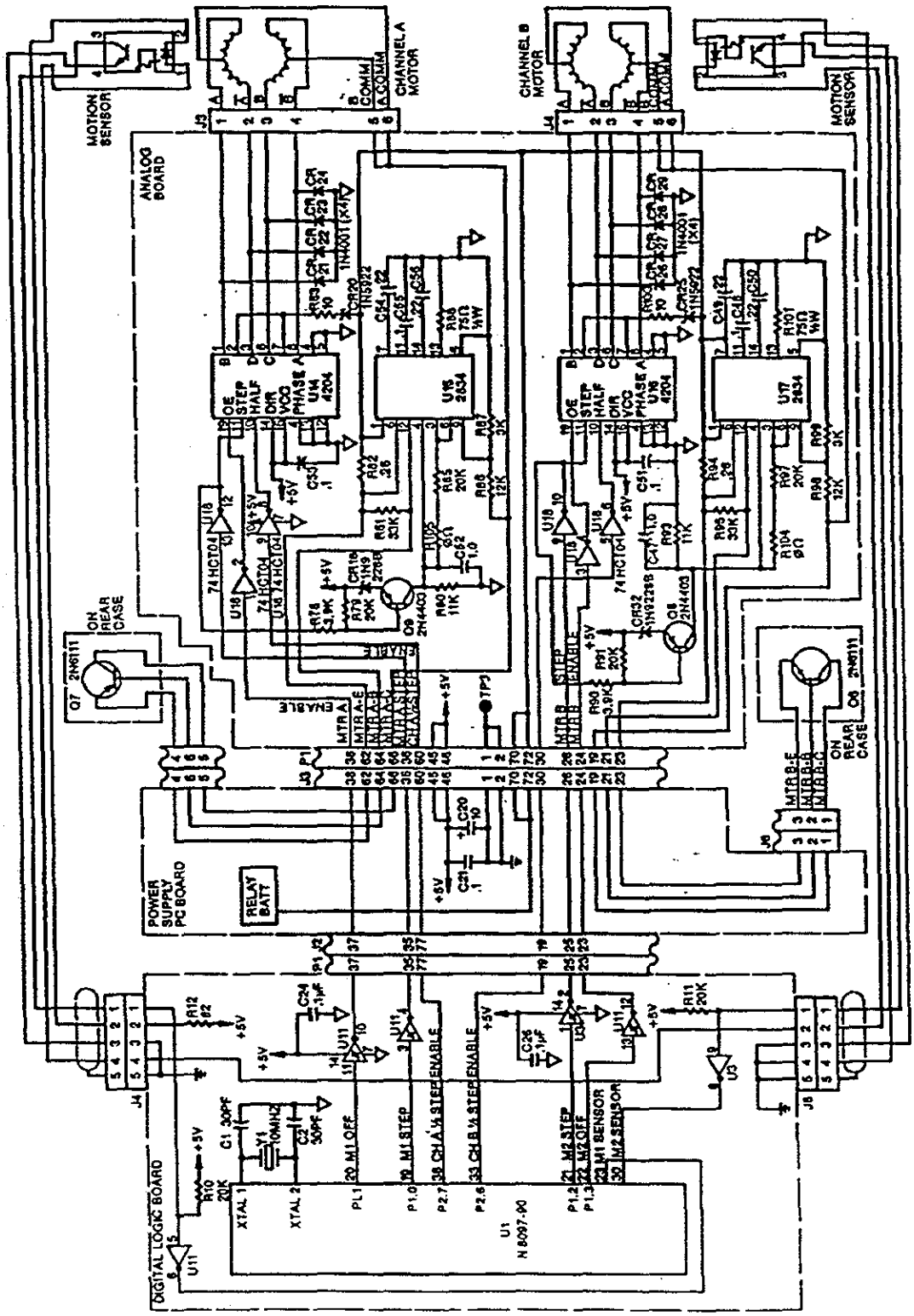
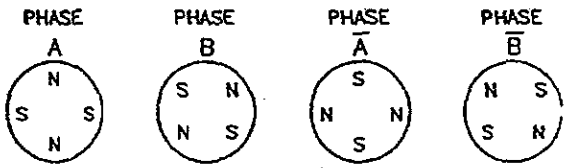


Figure 4-10. Pumping Mechanism - Functional Schematic [v2.xx]



The positional relationship between the central tooth on a stator pole and the rotor is shown with the A phase energized in Figure 4-11. When the B phase is energized and the stator polarity changes 45°, the rotor turns to align teeth 7/7' and 32'/31, a 1.8° rotation. Rotational realignment occurs as each motor winding phase is sequentially energized and the stator polarity changes 45° clockwise. This stepper motor configuration provides 200 incremental motor steps per revolution.

The pumping mechanism electrical interface utilizes dual phase excitation and a unipolar, current limited driver. Figure 4-12 depicts the input signal pulses and change in phase excitation of a unipolar driver. Motor drive current is initially supplied at 500mA minimum for 5 msec; then it is allowed to decay over a 10 msec time constant to 170mA minimum where it remains until the next step is commanded.

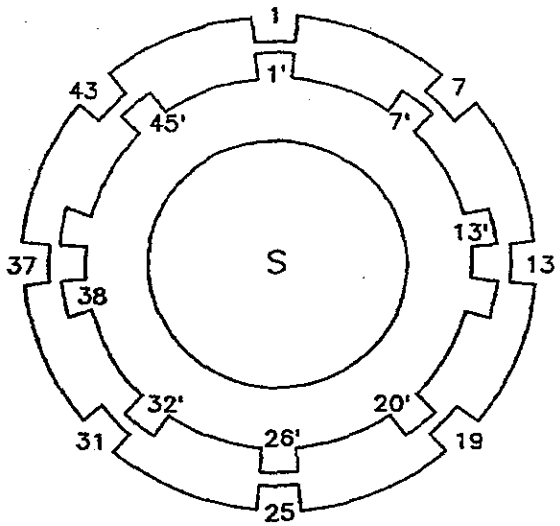


Figure 4-11. Relationship of Stator and Rotor Teeth with the A Phase Energized

The motor drive frequency range of operation is between 0.05 and 333 Hz. The nominal motor drive frequency is a function of the instrument's programmed infusion rate. This rate is software modulated to provide inter-step timing that will yield a linear fluid flow pattern. Software can also increase the nominal rate as much as 10% to compensate for periods of 'low flow'. To initiate a motor step, the microprocessor provides a signal through U3, U11 and U18 to enable the stepper motor driver (U14). The motor step signal is processed through U11 and U18 to pin 11 on the motor driver. Logic within the motor driver determines the motor phases to be energized. The motor step signal also turns on transistor (Q9) which allows the voltage on the ***threshold adjust*** (pin 4) of the current regulator (U15) to increase to ≈1.5VDC. This increase energizes the base of the pass transistor (Q7) which provides the current to turn the motor. Software controls the pulse width of the step signal at 3msec. When Q9 turns off, voltage at the threshold adjust degrades to 0.5VDC over a 10msec time constant (established by R80 and C52) and is then clamped at 0.5VDC by diode CR19 and the voltage divider R84 and R85. These two voltage levels result in the current being controlled at 500mA to turn the motor and 170mA to dampen and hold the motor in the new position. Diodes CR21 through 24 protect the motor driver from feedback of induced current.

The microprocessor monitors the signal from the motion sensor comparing it with the output to the motor driver as a rate accuracy check.

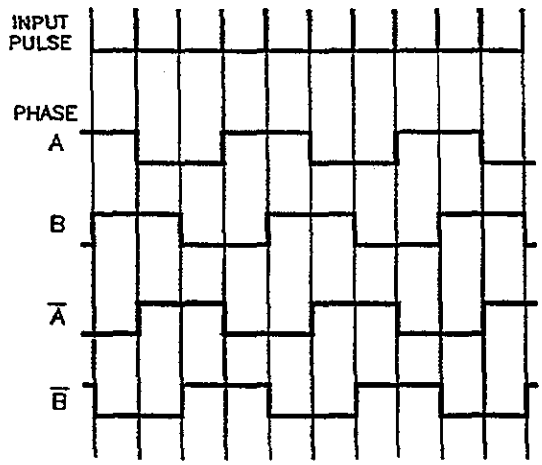


Figure 4-12. Input Signal Pulses and Change in Phase Excitation of Unipolar Drive.

NOTE

The 1/2 step circuitry shown on Figure 4-10 is not used in the instrument's current configuration.

Fractional Keypad/Series v3.xx Software

The chopper drive circuits (Figure 4-27, sheet 1, grid A1 to B10) provide an efficient means of converting the battery voltage to a lower variable voltage required by the stepper motors. These circuits are another form of switching regulator made up from discrete components.

A 50 khz oscillator is formed by U9 and associated components. The output at U9-1 is a 50 khz, 0 to 5 volt square wave. When applied to the rc network (R49, C25), a triangular waveform is produced and applied to comparitor U6-3. When the control signal at R38 is decreased or increased, the output at U10-7 is increased or decreased respectively. When applied to U6-2 and compared to U10-3, the output at U6-1 will be a 50khz variable duty cycle waveform. This waveform is level shifted via Q9 and applied to the gates of Q2 and Q5. The result is a variable duty cycle waveform at the drains of Q2 and Q5. When filtered by l3 and C19 a filtered voltage is produced inversely proportional to the voltage applied to the control input. When combined with the error amplifier located on the logic board, and the loop closed around the stepper motor, a constant current drive is the result.

4.3.2.8 Strain Beam

The PC-2 employes two identical, independent strain gauge subsystems to input administration set pressures to the microprocessor through the integral Analog to Digital converter. The subsystem includes a matched resistor bridge on the pressure sensing beam and a signal conditioning circuit (Figure 4-29, sheet 3, grid A1 to B10). Each leg of the resistor bridge is nominally 1200Ω. The Zero Balance Specification is $0.3mV/V_{EX}$. With no load applied to the beam and 5 volts excitation the Zero offset output will be ≤1.5 mV. Application of a positive force up to the 1 pound maximum load on the strain beam will lower the resistivity of the resistors in compression and increase the resistivity of the resistors in tension. At full deflection this will produce a 5 to 10mV change in output voltage. The signal conditioning circuit provides amplification and offset compensation to the low level signal output by the resistor bridge.

NOTE

All references to components by reference designator are for components comprising the channel A segment of the strain beam functional schematic.

The primary amplifier is a conventional three op-amp, balanced differential to single ended instrumentation type. The first stage uses a matched pair of op-amps for input signal tracking. The gain of this stage is determined by resistors R3, R4 and R5 in accordance with the following formula:

$$A = 1 + \frac{(R4 + R5)}{R3} \quad \text{(v2.xx only)}$$

$$A = 1 + \frac{(RA8a + RA8c)}{R55} \quad \text{(v3.xx only)}$$

The following stage is a balanced differential to single ended type with a gain of 1. The output of the offset amplifier is connected to the output of the second stage of the primary amplifier through resistor R15(v2.xx) RA8e(v3.xx). This provides an output at U4(v2.xx) U21(v3.xx) pin 1 of strain beam voltage x 420 plus the offset voltage. This allows the contributions of gauge offset and pre-load associated with the pumping chamber tubing set to be balanced with one adjustment. The output of U4(v2.xx) U21(v3.xx) pin 1 is further amplified through a subsequent stage with a gain variable between 1 and 6. This stage incorporates a diode (CR30[v2.xx] CR11[v3.xx]) between the output and the feedback divider which prevents the output from going negative. A post amplification filter consisting of R18(v2.xx) R62(v3.xx) and C10(v2.xx) C52(v3.xx) rolls off the gain at about 40Hz. The Schottky diode (CR1[v2.xx] CR12[v3.xx]) clamps the output voltage at V_{CC} + .3V. This signal is then supplied to the Analog input on the microprocessor for digital conversion.

Software Release v2.13 ONLY

The microprocessor's internal A/D converter has 10 bit resolution capability; however, in this application the least significant bit is discarded leaving 9 bits usable which yields a per bit resolution ratio of 1:512. Using a reference voltage set at 5V, each bit is equal to $^5/_{512}$ or ≈9.76mV. The strain beam calibration process involves applying known pressures and then adjusting the gain and offset (SPAN and ZERO) balance of the signal conditioner to yield set voltages. Since the converter is unipolar and will only process signals in the range of 0 to V_{REF}, the calibration points are established at 0 and 10 psi which correspond to 1.5 and 4.5 volts respectively. The 10 psi differential between calibration limits equates to 3.0 volts. On a 5 volt scale this equates to using $^3/_5$ of the available scale, i.e. $^3/_5$ of the 512 bits or 307 bits. Converting psi to inches of water pressure, the 10 psi differential equals 332 inches of water

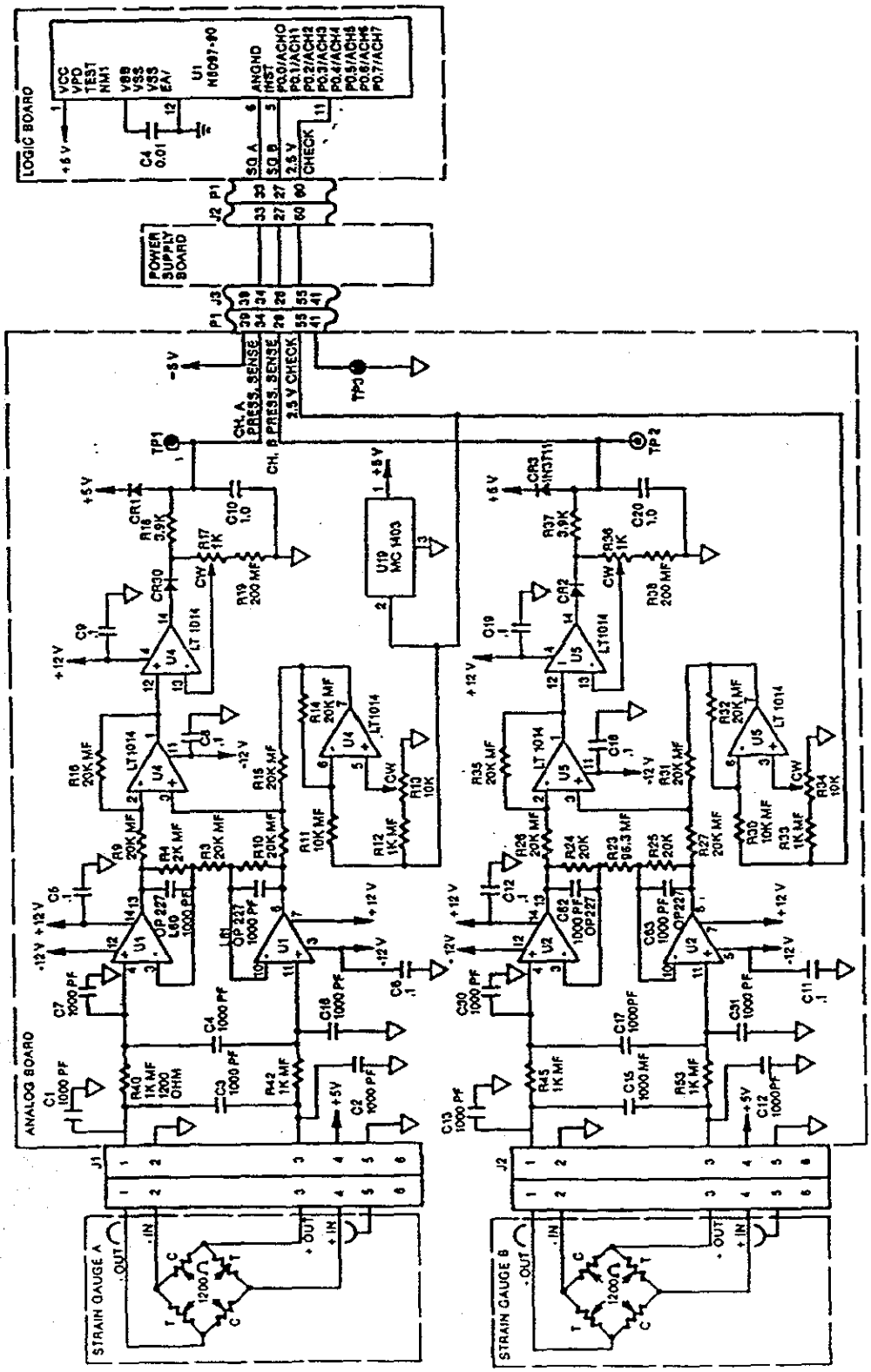


Figure 4-13. Strain Beam - Functional Schematic [v2.xx]

pressure. This establishes the resolution of the converter at 1.08 inches per bit. Setting the 0 psi value equal to 1.5 volts allows the system to recognize and measure pressures less than atmospheric which can occur during an upstream occlusion. In addition, the strain beam will also detect the presence of an administration set in the pumping chamber.

4.3.2.9 Air-In-Line Detector

The active elements of the PC-2's air-in-line detection system includes two piezo-electric (PE) crystals and a hybrid integrated control circuit. The PE crystals and acoustic lenses are bonded into recesses in the AIL/SCD housing (see Figure 4-14). The hybrid circuit is part of the AIL/SCD printed circuit board. Ultrasonic sensing is used for air-in-line detection since ultrasonic wave transmission is independent of fluid opacity. Ultrasonic signal transmission (acoustic impedance) through all IV compatible solutions falls within a very discrete range which is easily discernable from passage through air.

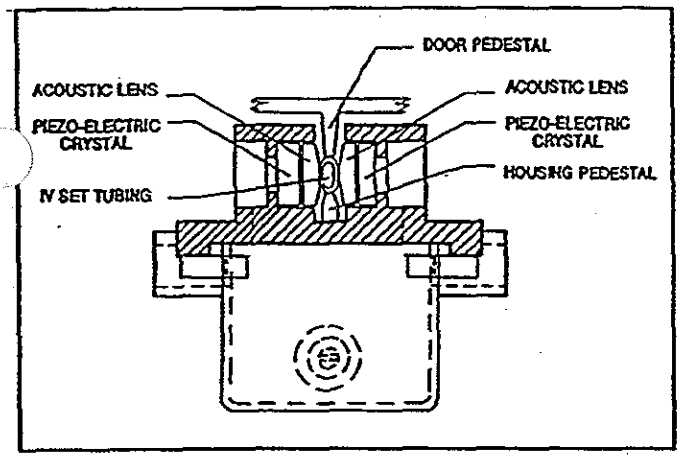
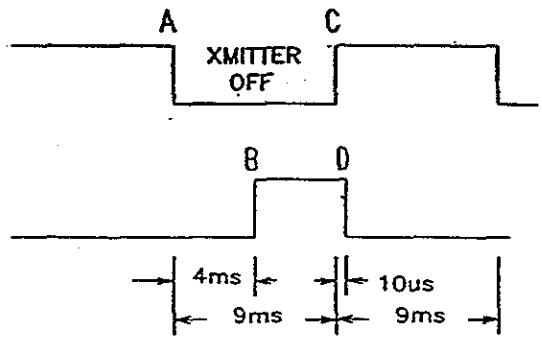


Figure 4-14. Cross Section of AIL Detector

The air-in-line detector is located below the pumping mechanism and checks the integrity of the fluid column entering the patient side (distal portion) of the tubing set. The acoustic lenses and installed tubing set provide a coupling path for the continuous wave ultrasonic transmission to travel from the transmitting to the receiving crystal. When the tubing contains an IV solution the acoustic impedance is low and maximum energy is coupled to the receiving element which generates a voltage signal that is proportional in amplitude to the coupled energy. If an air bolus is interposed between the lenses the acoustic impedance is significantly increased as the acoustic wave is reflected by the liquid-air interface. The energy received is reduced and the voltage output is commensurately reduced. This signal differentiation combined with the instruments programmed delivery rate is used to measure the volume of the air bolus.

The digital circuity shown in Figures 4-15a, -15b or -15c drive the transmitter and detect, amplify and perform a threshold comparison on the received signal. The system is strobed by a software generated signal every 18 msecs to validate system operation. A filter within the logic circuit creates a time delay between the transmitter Off cycle and a state change in the receiver output. Because the strobe is software generated, the wave form is non-uniform. A nominal timing wave has the form depicted below:



The output of the AIL circuit is sampled just prior to the strobe changing state which yields the following truth table:

		AIL HI	AIL LO
TRANSITION	A	AIR	LIQUID
TRANSITION	C	CKT OK	CKT FAULT

The transition at point B always occurs approximately 4 ms later than the transition at A; however, circuit tolerances and signal levels can cause this delay to vary as much as ±2 ms.

The calculation of air bolus size is based on the assumption that at a given delivery rate air and fluid will pass through the sensor at a uniform rate. The length of time required for an air bolus to pass through the detector is measured by counting the number of timing interrupts when the sensor is "seeing" air. Time is therefore measured in number of interrupts per bolus. When the resultant time exceeds the time required for 38 motor steps the instrument enters an "AIR-IN-LINE" alarm condition.

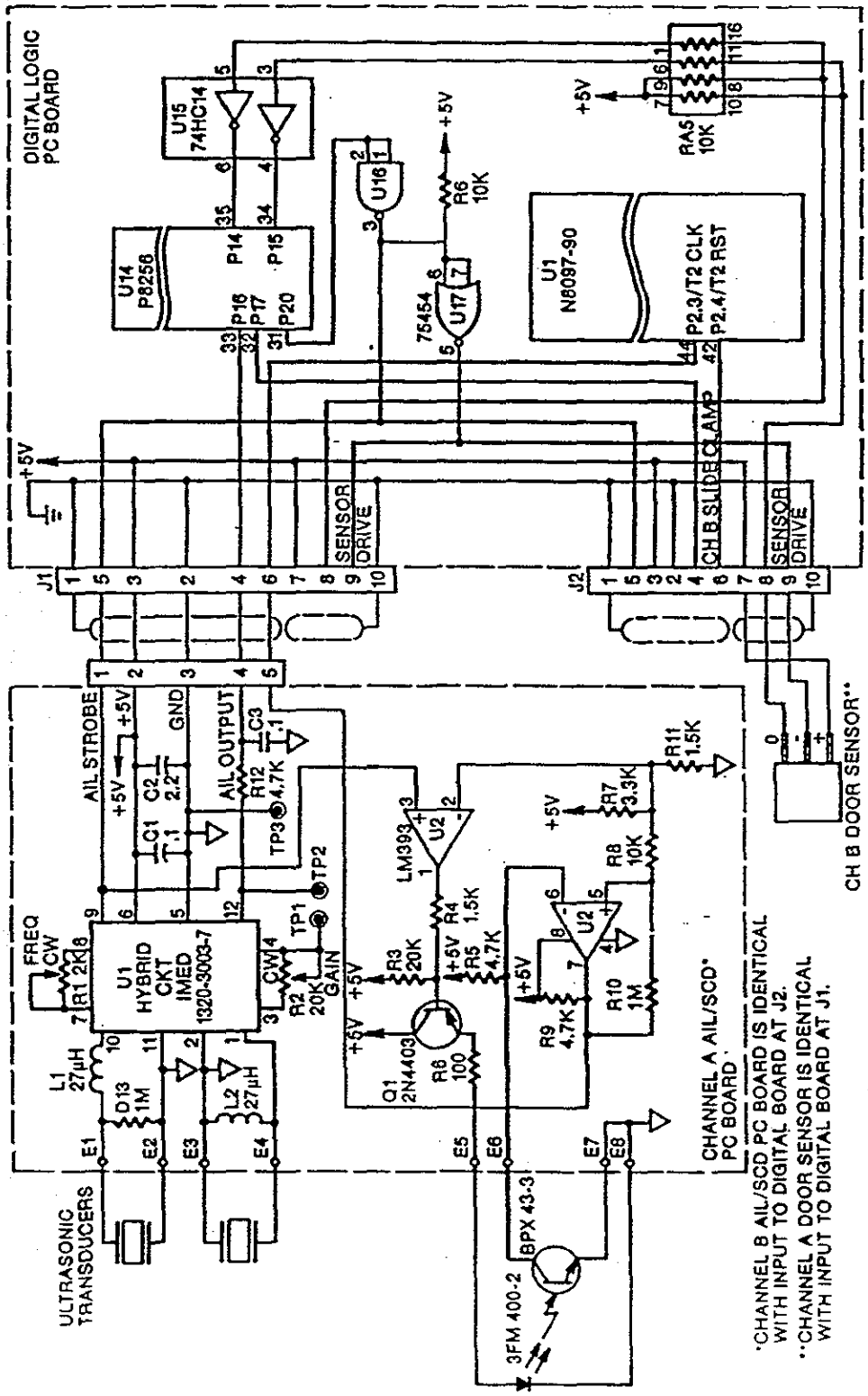


Figure 4-15a. AIL/SCD/Door Sensor - Functional Schematic [v2.xx]

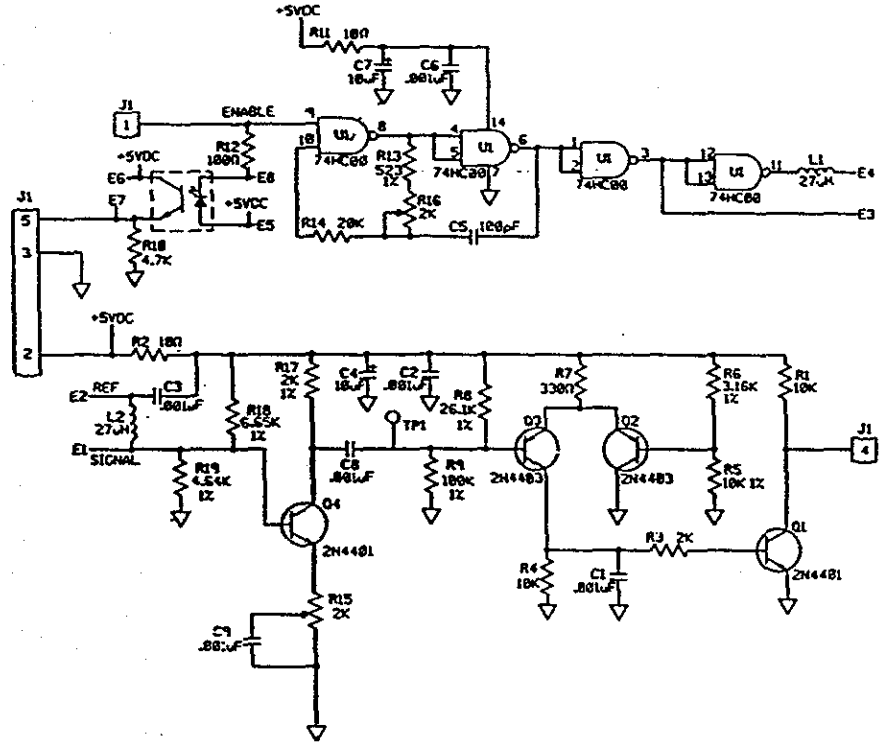


Figure 4-15b. AIL/SCD PCB Schematic — 20-5000

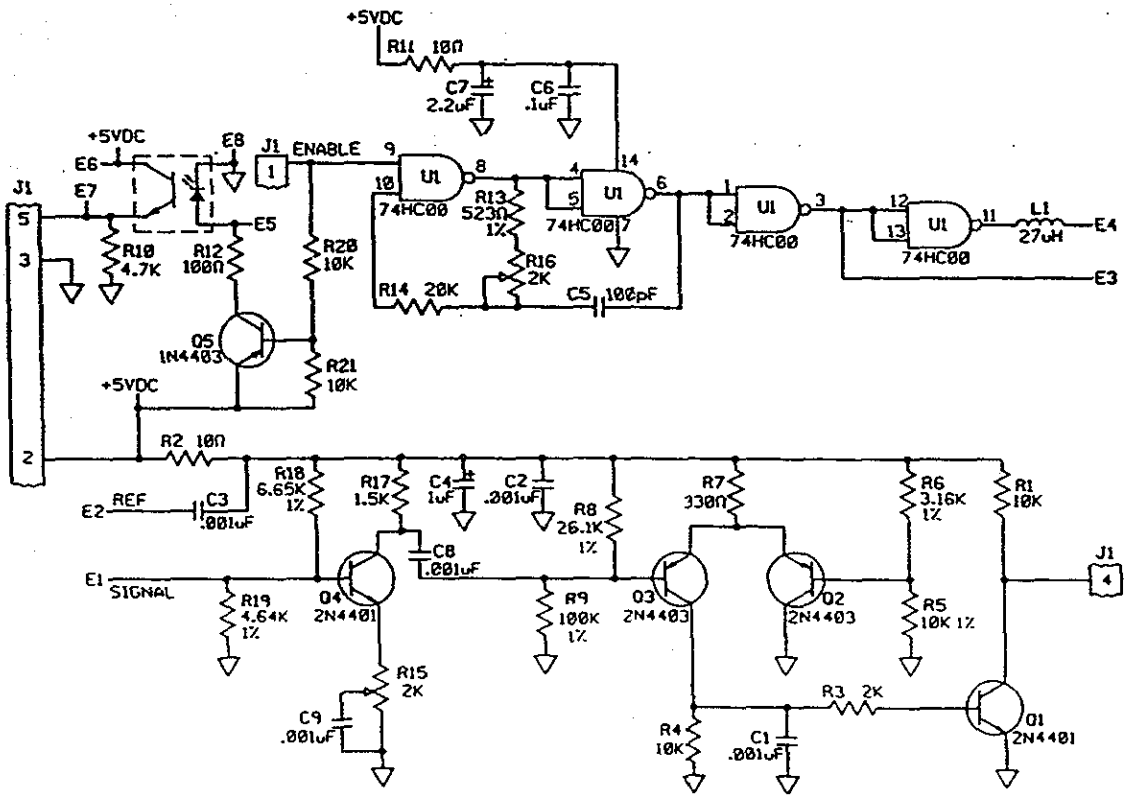


Figure 4-15c. AIL/SCD PCB Schematic — 20-5012

4.3.2.10 Slide Clamp Detector

The slide clamp detection subsystem consists of a photo diode and transistor plus a signal control and comparator circuit. The photo diode and transistor are mounted diametrically on the sides of the slide clamp recess on the AIL/SCD housing (see Figure 4-16). The signal processing circuitry for the slide clamp is incorporated into the AIL/SCD printed circuit board

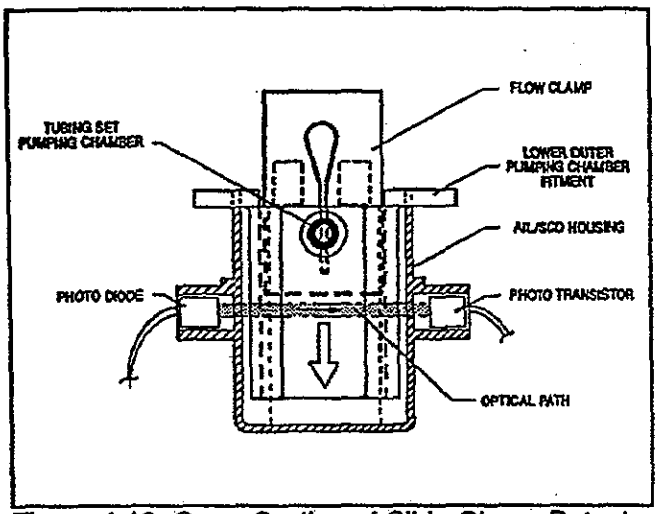


Figure 4-16. Cross Section of Slide Clamp Detector

When the slide clamp circuit is energized, a beam of light is projected across the slide clamp recess. The beam is positioned at a point where movement of the slide clamp towards "open" will interrupt the light beam just before free flow occurs in the tubing. If the light path is interrupted with the pumping chamber access door open, the instrument will enter a "FLO STOP OPEN / CLOSE DOOR" alarm condition.

Current to the photo diode is switched on and off by transistor Q1 and one half of the dual comparator (see Figure 4-15). One input to the first stage of the comparator is the DC reference voltage which is by the resistor divider R7 and R11. The other input is the processor logic strobe with a period of 18 msec and a 50% duty cycle. When the strobe is in the low state current flows through the photo diode. When the optical path is not interrupted current is induced on the photo transistor. This current then flows through R5 causing the voltage at the inverting input to the second comparator to go below the reference voltage at the non-inverting input. This results in the output of the comparator going high. When the optical path is interrupted or the strobe duty cycle is high the output of the second comparator will be low. The output of the second comparator is sent to the microcontroller for analysis and determination of alarm condition or normal operation.

4.3.2.11 Door Sensor

The door sensor subsystem consists of a Hall Effect sensor and the logic circuitry necessary to query the sensor and to determine Open or Closed status and report the existing condition to the processor. The Hall Effect sensors are located on the rear of the front case insert assembly 2.375 inches directly below each anchor bracket assembly (see items 70 & 400, Fig 6-1c). The magnet is attached to a pedestal on the backside of the door latch handle (Fig 6-2). The components of the door sensor logic circuit are incorporated on the Logic PC board (see Figure 4-15).

<u>Integer Keypad/Series v2.xx Software</u>
The door sensor is enabled by a strobe from the main processor through the I/O expander (U14). The strobe passes through a non-inverting driver (U16 & U17) emerging as a low. With the sensor enabled and the door open, the sensor sends a high through RA5 to the signal conditioner (U15). There the signal is inverted and inputted to the I/O expander as a low. When the door is closed, a low is sent to the signal conditioner, is inverted and inputted to the I/O expander as a high. The processor analyzes the sensor signal to make a normal operation or alarm condition determination.

<u>Fractional Keypad/Series v3.xx Software</u>
The door sensor is enabled by a strobe from the main processor through the custom ic (U2). The strobe drives the gate of MOSFETin U17 pin 12. With the sensor enabled and the door open, the sensor sends a high to the microprocessor U1 pin 21. The processor analyzes the sensor signal to make a normal operation or alarm condition determination.

4.3.2.12 Audio Subsystem

Integer Keypad/Series v2.xx Software

The audio subsystem consisting of an audio oscillator, audio system control circuitry and volume control/silence switch. The audio oscillator is attached to the inside of the rear case over the audio alert aperture. The system circuitry is incorporated into the Analog Board and the audio adjust/silence control is mounted on the rear panel. The functional schematic for the Audio system is shown in Figure 4-17. During normal instrument operation, an audio pulse is sent from the I/O expander (U14) to the base of transistor Q5, Q6 or Q7 to produce an audio signal of the required period and intensity. Audio signals that permit volume adjustment and silencing are routed through Q7. Keypress signals are routed through Q6 and are limited in volume intensity by R67. Malfunction audio which is projected at maximum volume is routed through Q5. Audio signals resulting from power loss or watchdog detection are initiated through the audio logic circuit. With the instrument on, loss of +5VDC will cause the output of U10 pin 6 to go high resetting the U9 latch. Output at U9 pin 1 will be low resulting in the output of U13 pin 6 being high. The high output of U13 pin 6 will activate the base of Q3 which initiates the audio oscillator. Watchdog detection during instrument operation will cause the output of U12 pin 10 to go high setting the latch U9. Output of U9 pin 15 will be high to U13 pin 9. U13 pin 8 output will be low to U13 pin 13 and the output of U13 pin 11 will be high activating the base of Q3 which initiates the audio oscillator.

Fractional Keypad/Series v3.xx Software

The audio subsystem (Figure 4-29, sheet 2, grid D6 to D8) consisting of an audio transducer, audio system control circuitry and volume control/silence switch. The audio transducer is attached to the inside of the rear case over the audio port in the rear case. The audio logic is implemented in the custom ic U16 on the logic board along with the audio drivers Q2 thru Q5. During normal instrument operation, an audio pulse is generated by the microprocessor by writing to one of three address decoded in U16. A fourth address is decoded by U16 to reset the audio. The outputs, pins 16,17 and 18 drive the base of transistors Q3, Q4 or Q5 to produce an audio signal of the required period and intensity. Audio signals that permit volume adjustment and silencing are routed through Q3. Keypress signals are routed through Q4 and are limited in volume intensity by RA7c. Malfunction audio which is projected at maximum volume is routed through Q5. Audio signals resulting from power loss or watchdog detection are initiated through the audio logic circuit. With the instrument on, loss of +5VDC will cause the reset signal to go low since the comparator U12 is open collector output pulled up to 5V by R40. This is detected and interpreted by U16 as a vcc loss and in turn generates a max audio output on pin 18. Watchdog detection during instrument operation is occompished by the watchdog circuit setting U16 pin 22 high. The logic in U16 determines this condition and generates a max audio on pin 18 and enables the power on switch to power off the instrument.

4.3.2.13 Display Subsystem

The Display Subsystem consists of five subordinated elements that are interactive and collectively provide the user interface. The Operator Information (message) displays consisting of eight 5 x 7 dot matrix arrays per channel and are capable of presenting all the upper and lower case alphabetic characters, numbers 0 - 9 plus ?, (,), = and /. The control circuit includes the oscillator for the scan clock, the system interface logic, the character decoding logic and the display drivers (see figure 4-18). The selected scan frequency prevents visual detection of flicker. The message arrays interface with the logic system controller bus. The interface includes the lower eight bits of the data bus, AD0 to AD7; four address lines A0 to A2 plus logic enable; four data write strobes that are decoded by wait logic to extend cycle times for display compatibility and a negative true reset signal with a 50 msec pulse width. All command signals are CMOS compatible and positive true unless described otherwise.

The RATE and VTBI displays each consist of four 7-segment LEDs plus the decimal point option and include a control circuit for segment error detection (see Figure 4-19). The RATE/VTBI displays interface with the logic subsystem controller bus. The interface is comprised of the lower eight bits of the data bus, AD0 - AD7; four decoded address

lines, A0 - A2 plus logic enable; two data strobes; write\; read\ and system reset. The slave processor U7 provides scanning and formatting and outs characters through port 1 and segment control through port 2. All signals are CMOS compatible and positive true unless described otherwise. Reset signal is negative true. The control logic detects failures in the LED segments and drive circuitry due to shorts or opens and reports the condition to the logic subsystem. Figure 4-20 shows the functional schematic for the Segment Check/Error Detection circuitry.
The instrument also incorporates seventeen discrete LEDs that are individually addressable and are used to display the status of user interface selections and instrument operating status. Twelve of the LEDs are used in the Delivery mode/Relative Rate Indicator displays, two are used to indicate channel access, one is used to indicate active status of the Secondary infusion state, one indicates AC power is connected and the last indicates operation on battery power. Sixteen of the discrete LEDs interface with logic subsystem through the controller data bus (see Figure 4-19). The interface consists of the lower eight bits of the data bus, AD0 -AD7; two decoded address lines, LED1 and LED2 which are connected to the write enable pins (WE1) on U1 and U2 latched drivers and the data write strobe. The AC connected indicator interfaces directly with the power supply subsystem.

The keypad interface and decoder is mounted on the display board. The interface consists of a keypad controller, an octal latch to connect with the controller bus and a keypad/board interconnect cable (see Figure 4-21 [v2.xx] or Figure 4-28, sheet 2, grid E2 to F9 [v3.xx]).

Three indicator lamps are provided for user serial interface when the instrument is used in conjunction with a host computer system. The COMPUTER CONTROL and MONITOR indicators, are LED back-lighted and the other is a discrete LED which responds to communication traffic between the instrument and host computer. Figures 4-19 and 4-22 show the functional relationship of the computer related indicators to the microprocessor.

4.3.2.14 Nurse Call

Integer Keypad/Series v2.xx Software
The Nurse Call subsystem consists of an interface connector mounted on the channel B communication board and an operating circuit integrated into the digital logic board (see Figure 4-23). The interface connector accepts the plug from the facility's Nurse Call system and allows the PC-2 to act as a switch to actuate the system.

During normal instrument operation (Nurse Call system - not activated) processor output to the Nurse Call circuit is high. When the processor detects a condition (malfunction, alarm or "Press Start" prompt) that dictates activation of the Nurse Call system, a low is sent through the I/O expander (U14, pin 26), is inverted at U11 and is sent as a high to pin 2 of NOR gate U17. The output of U17 at pin 3 goes low allowing current to flow through the K1 relay coil, closing the contacts and actuating the Nurse Call system. A watchdog malfunction will input a high at U17 pin 1 causing the output of the gate to go low, energizing the K1 relay coil and activating the Nurse Call system.

Fractional Keypad/Series v3.xx Software
The Nurse Call subsystem consists of an interface connector mounted on the channel B communication board associated logic circuit residing on the digital logic board (Figure 4-29, sheet 2, grid B1 to B5). The control logic is implemented in the custom ic U16 and drives relay K1 by enabling/disabling a MOSFET in U17. The input drive is applied to the gate on U17 Pin 10 and the output on pin 8 drives the nurse call relay K1. The nurse call function is enabled by software or a watchdog condition.

4.3.2.15 Communications Interface and Signal Definitions

To interface a host computer system with the PC-2, the interface cable must be configured with a 9-pin 'D' subminiature male connector with either a quick release or screwlock backshell with jackscrews for mechanical interconnection. Figure 4-24 illustrates the circuit for the RS-232-C Communications Data Port connector. Signal voltage levels are ±12VDC with 20m Amp. Signal

aracteristics conform to RS-232-C Standards. n 5 of the Communications Data Port connector is connected to logic ground on the communications board and is only to be used for common signal return for TxD, RxD, DTR, DSR, RTS and CTS. Pin 1 of the Data Port connector is not connected and is to be used only for protective shielding of the interface cable. The interface cable shield should only be attached to chassis ground on the host computer end of the cable. Pin 9 is not connected and should not be used. Table 4-1 defines the signals and identifies the pin numbers used to interface a host computer to the PC-2. The instrument utilizes IMED C2 Communications Protocol which can be found in the PC-2 Programmers Guide P/N 1320-9004.

NOTE

Maximum leakage current to chassis ground from connected ancillary equipment must not exceed 100µA.

4.3.2.16 Maintenance Mode

ne maintenance mode subsystem operation requires the presence of a plug for instruments configured with Software Release V2.13. The plug is installed in the Nurse Call/Maintenance Plug connector and is used to short pins 2 and 3. When the plug is installed and the POWER ON control actuated, a high signal is sent to U15 where it is inverted and enters the I/O expander as a low (see figure 4-25). Instruments configured with *Software Release V2.34* and subsequent utilize the COMPUTER CONTROL/MONITOR switch to access the maintenance mode. When the POWER ON control is pressed with the maintenance plug installed or the COMPUTER CONTROL/MONITOR switch depressed, the instrument will initialize in the maintenance mode. Software Release V2.13 configured instruments utilize the audio control switch to activate an unused pair in the keypad switch matrix and provides the input to the keypad decoder necessary for maintenance mode test selection. In *Software Release V2.34* configured instruments maintenance mode test selection is accomplished by actuating the COMPUTER CONTROL/MONITOR switch.

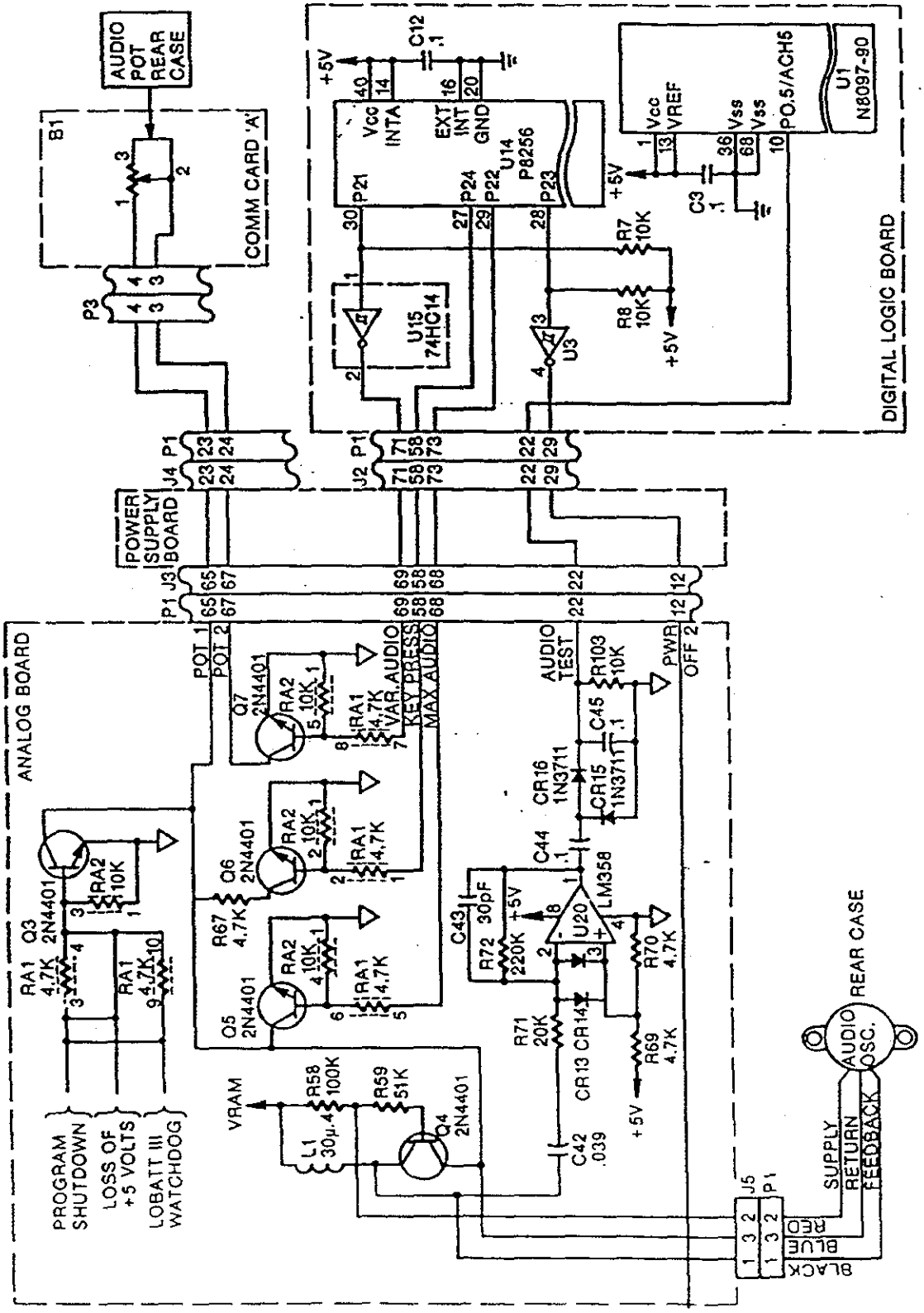


Figure 4-17. Audio Subsystem - Functional Schematic [v2.xx]

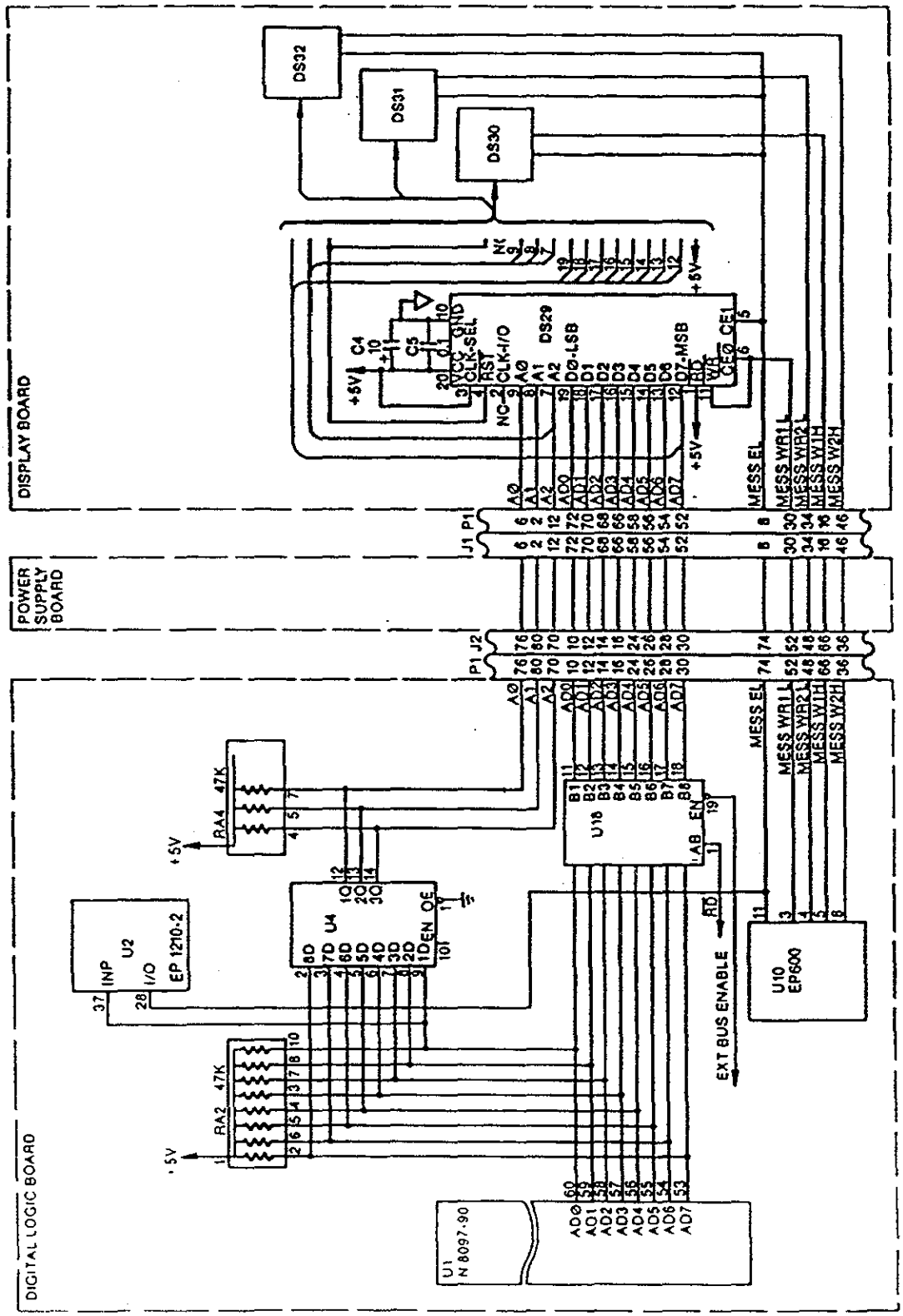


Figure 4-18. Operator Information Display - Functional Schematic [v2.xx]

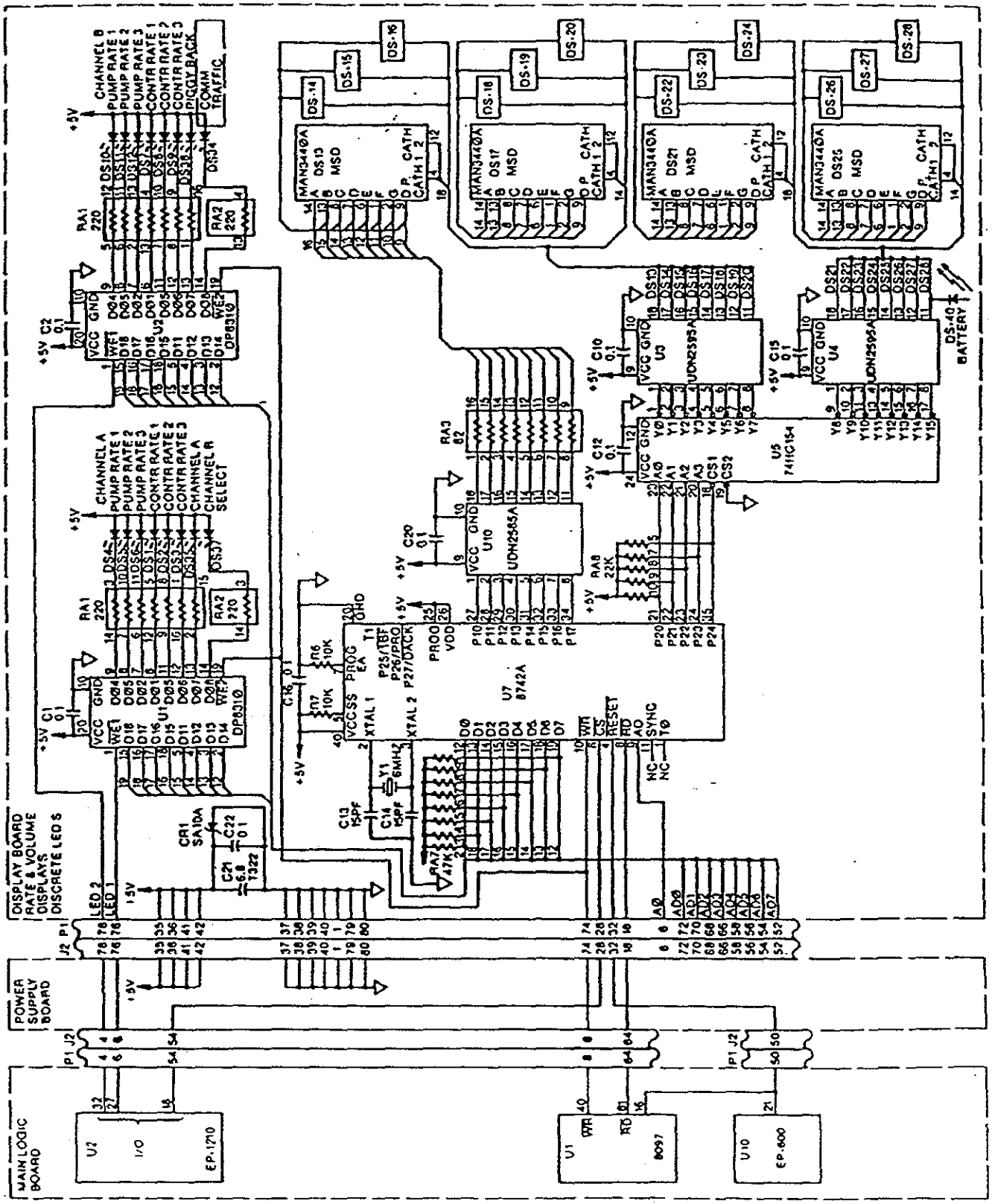


Figure 4-19. RATE, VTBI and Discrete LED Display - Functional Schematic [v2.xx]

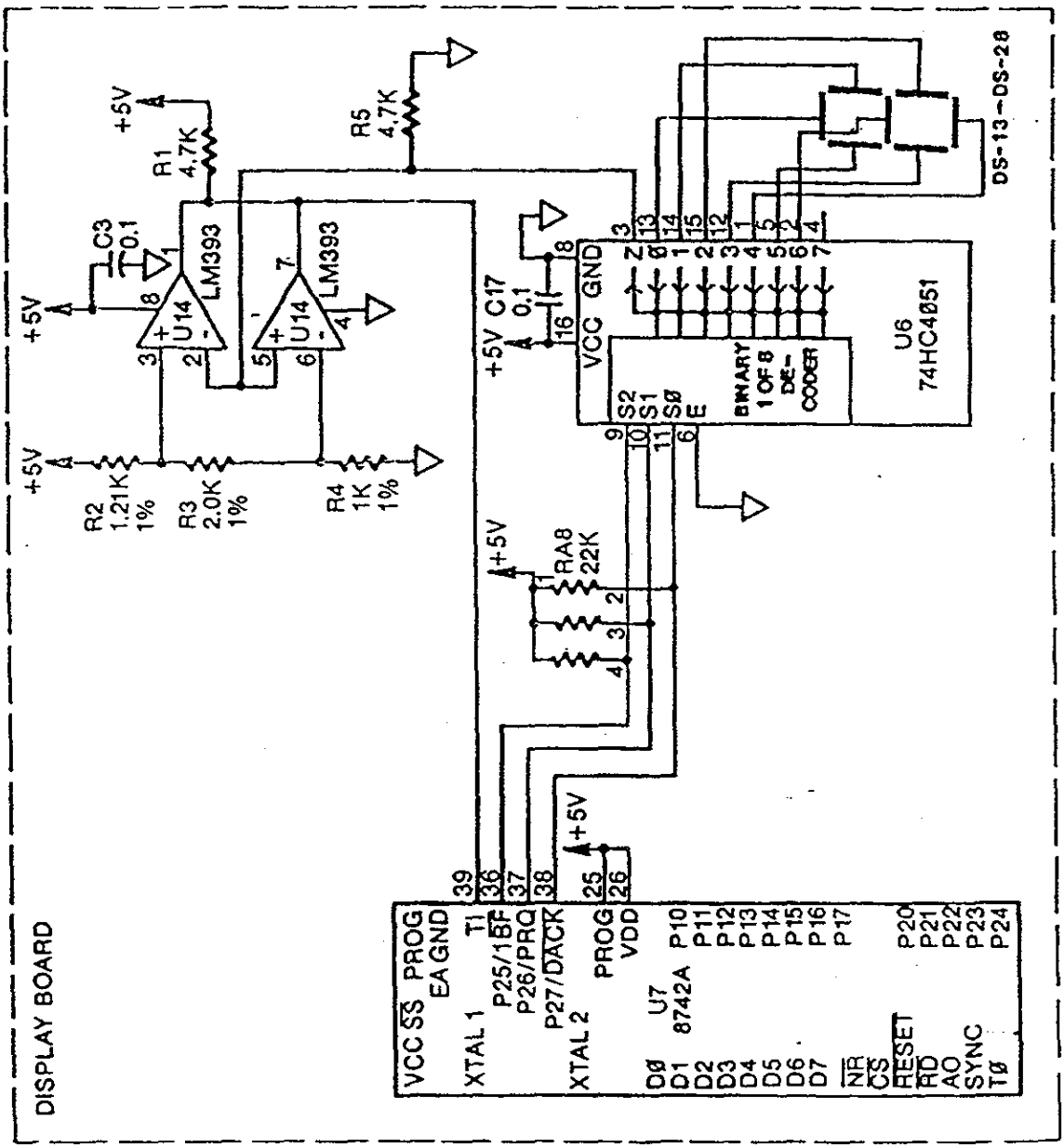


Figure 4-20. Segment Check/Error Detection Functional Schematic [v2.xx]

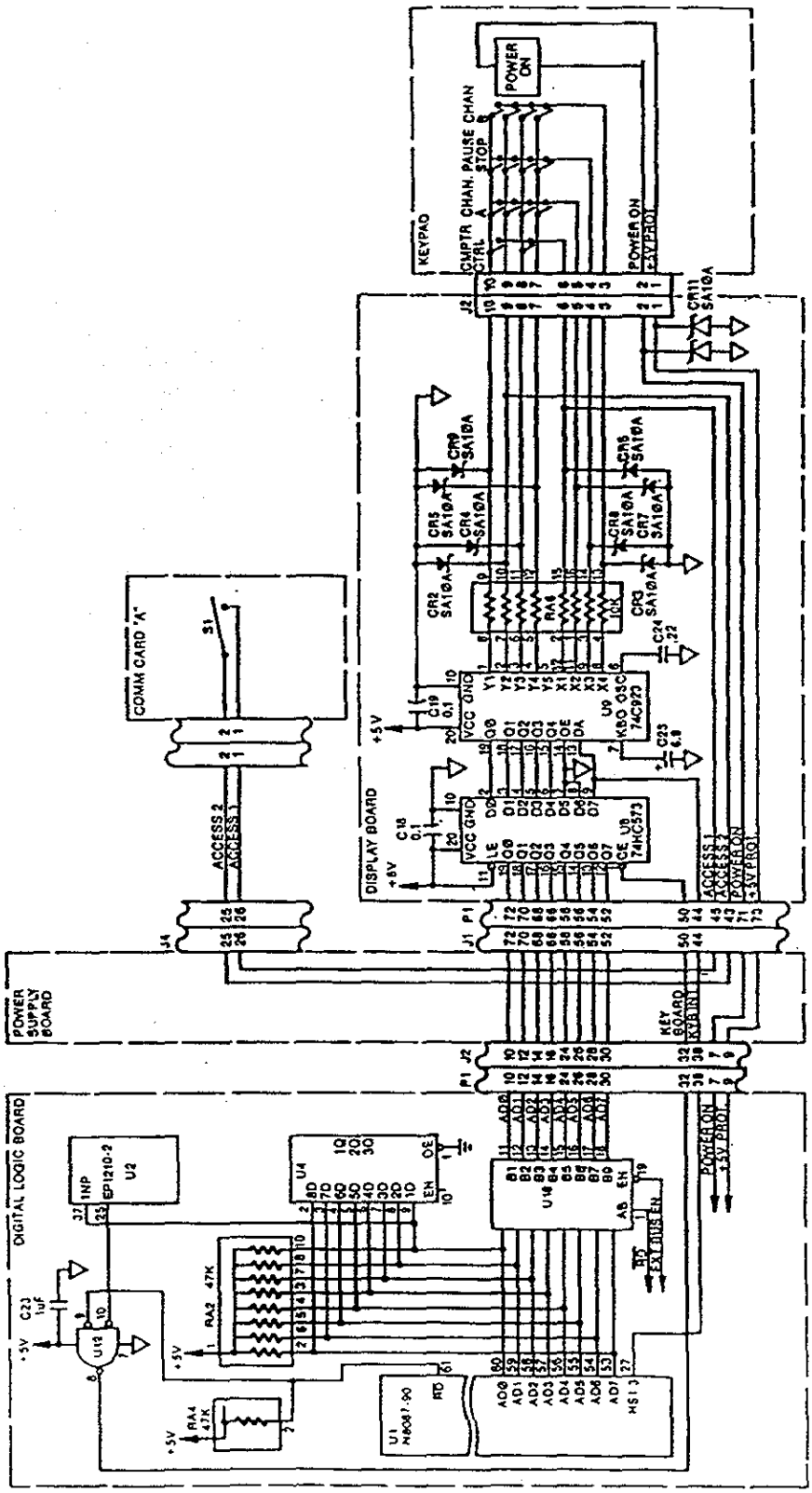


Figure 4-21. Keypad Interface - Functional Schematic [v2.xx]

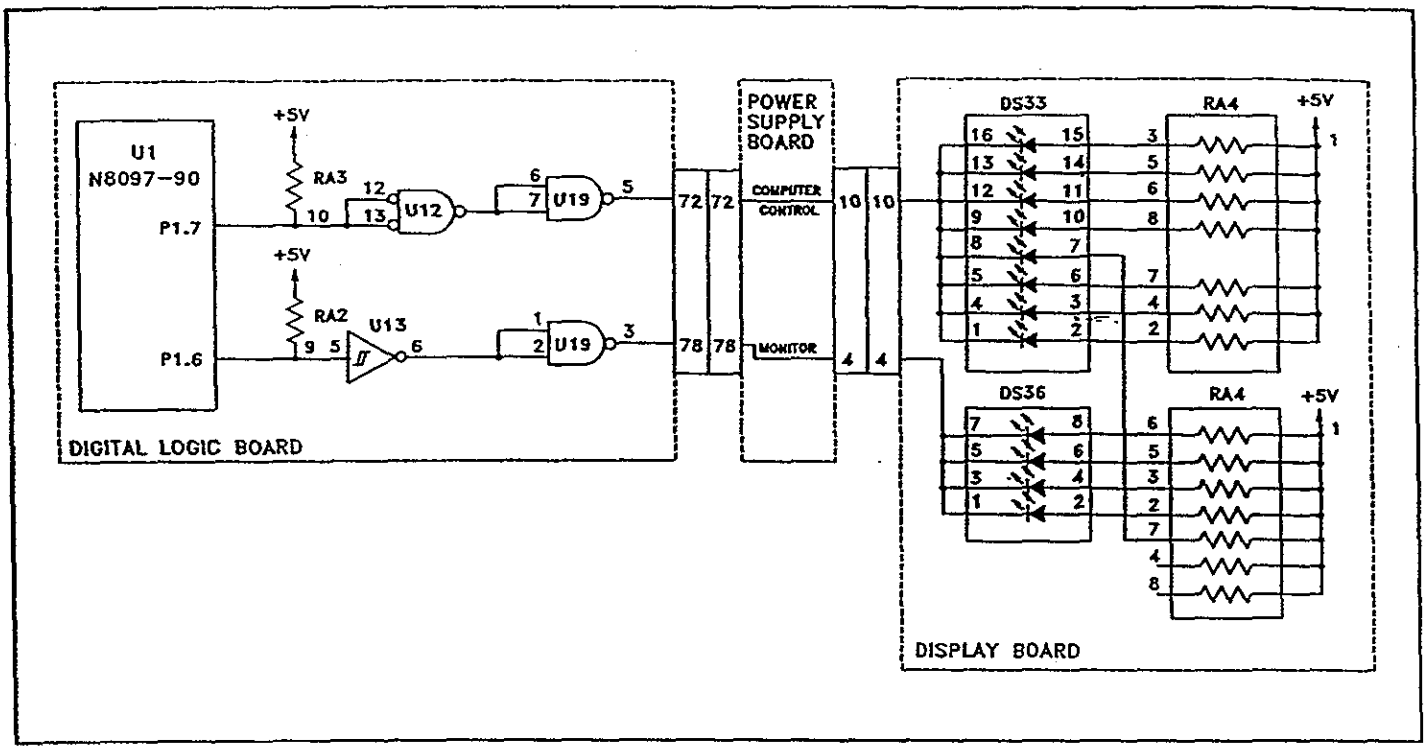


Figure 4-22. Computer Operation Indicators - Functional Schematic [v2.xx]

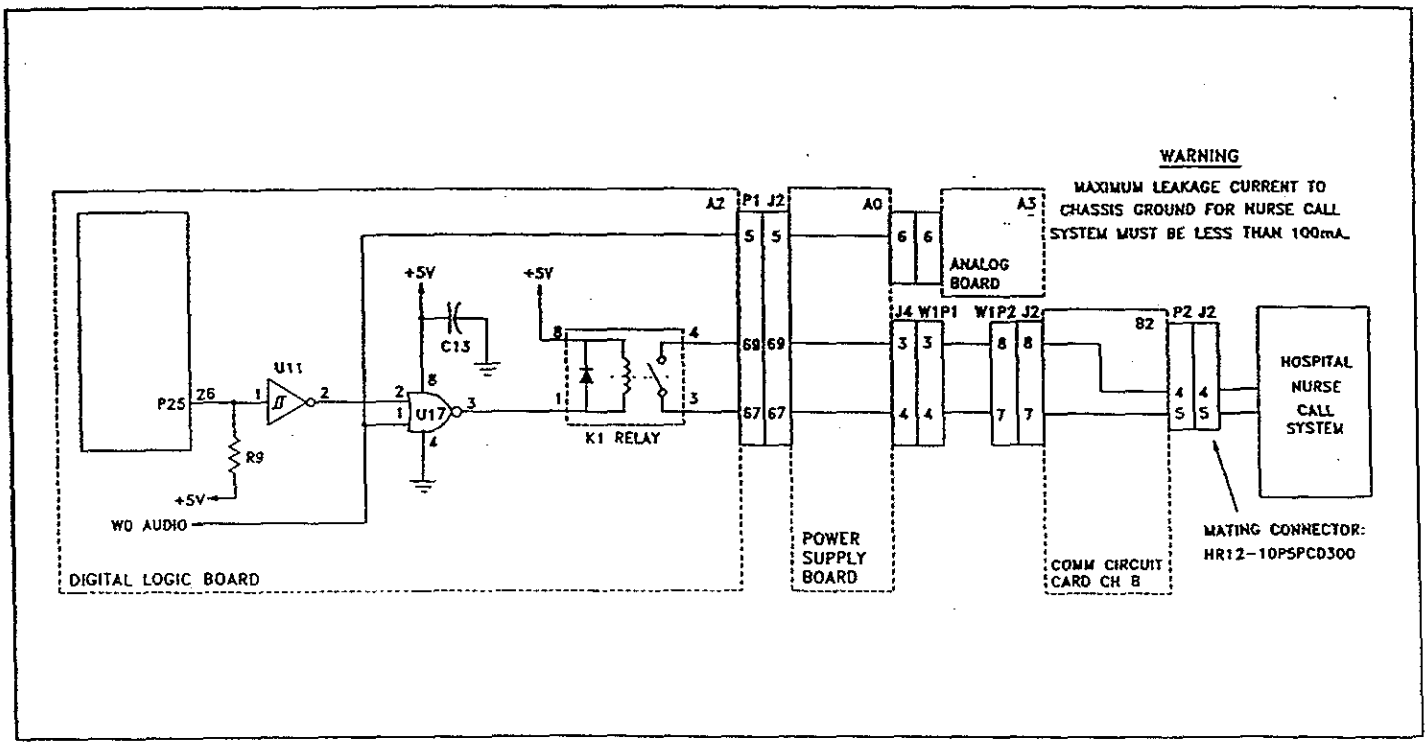


Figure 4-23. Nurse Call System - Functional Schematic [v2.xx]

Table 4-1. RS-232-C Communications Data Port Signal Definitions

Signal Name	Number	Directions	Definition
GND (Ground)	1	Host	Not tied to chassis ground on the PC-2. To be used only for protective shielding. The shield should only be connected to chassis ground on the host computer end.
TxD (Transmit Data)	3	PC-2 to Host	Serial data transmitted to host computer from PC-2.
RxD (Receive Data)	2	Host to PC-2	Serial data transmitted to PC-2 from host computer.
RTS (Request to Send)	7	PC-2 to Host	When asserted, RTS indicates to the host computer that the PC-2 has information to transmit. Can be used to tell the host computer to wait.
CTS (Clear to Send)	8	Host to PC-2	Asserted by the host computer to enable the PC-2 to transmit data.
DSR (Data Set Ready)	6	Host to PC-2	DSR indicates to the PC-2 that the host computer is capable of communications. (Connected and power on.)
Signal Ground	5	PC-2 to Host	Common signal return to TxD, RxD, DTR, DSR, RTS and CTS.
DTR (Data Terminal Ready)	4	PC-2 to Host	DTR indicates to host computer that the PC-2 is capable of communication. (Connected and power on.)
Not Connected	9		

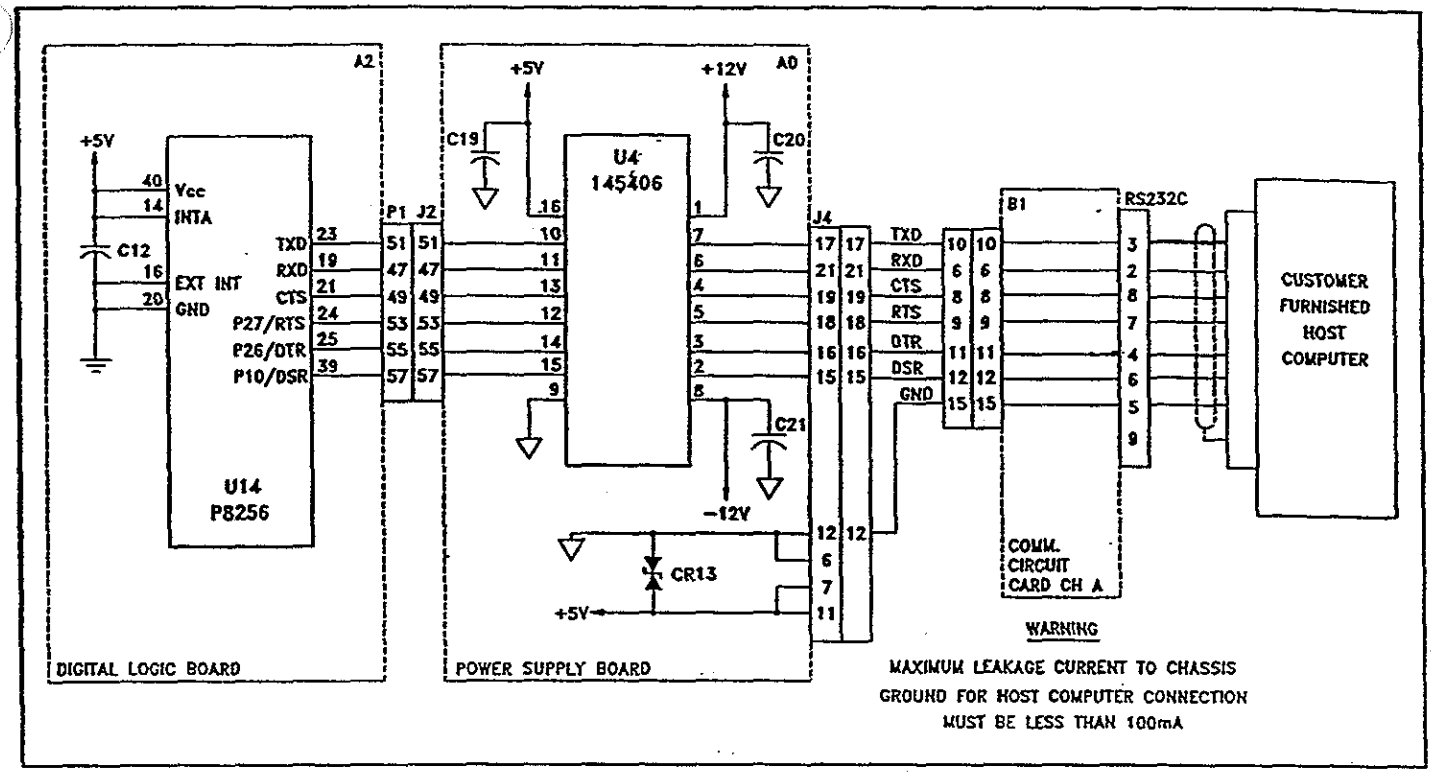


Figure 4-24. Communications Interface - Functional Schematic

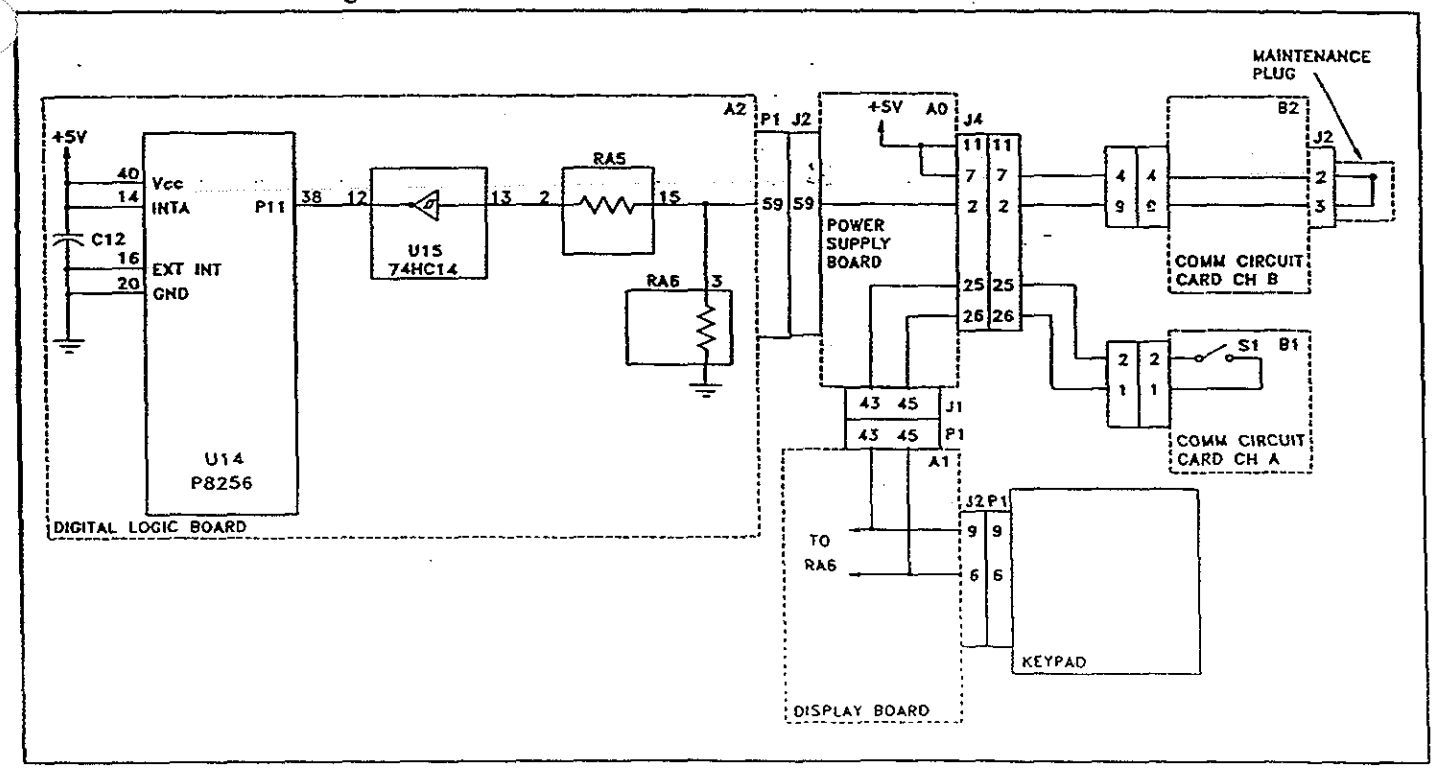


Figure 4-25. Maintenance Mode Subsystem (v2.13) - Functional Schematic

4.3.2.17 Empty Container Detector (ECD) (Optical)

The Empty Container Detector subsystem consists of an optical sensor with a signal amplifier and a signal conditioning circuit. The optical sensor and amplifier circuit are molded into the ECD assembly that attaches to the drip chamber of a primary administration set. An ECD can be used with each channel. The signal conditioning circuitry is incorporated on the digital logic board.

The microprocessor generates an ECD strobe to query the optical sensor. The strobe has the same duty cycle as the strobe used with the AIL detector subsystem (see section 4.3.2.2). Without an ECD connected the signal to the processor will always be read as a high. With an ECD connected and fluid in the drip chamber the light beam is refracted, the photo transistor does not see light and the ECD output signal is an inverted strobe signal which is read by the processor as a high. The detector's signal conditioning circuit (see Figure 4-26) uses a synchronous demodulator to minimize spurious signals resulting from ambient light reception. When the drip chamber empties synchronous pulsed light is sensed by the photo transistor and the ECD output signal goes high. This signal is inverted at U15 and is read by the processor as a low which results in the issue of an EMPTY CONTAINER-KVO advisory.

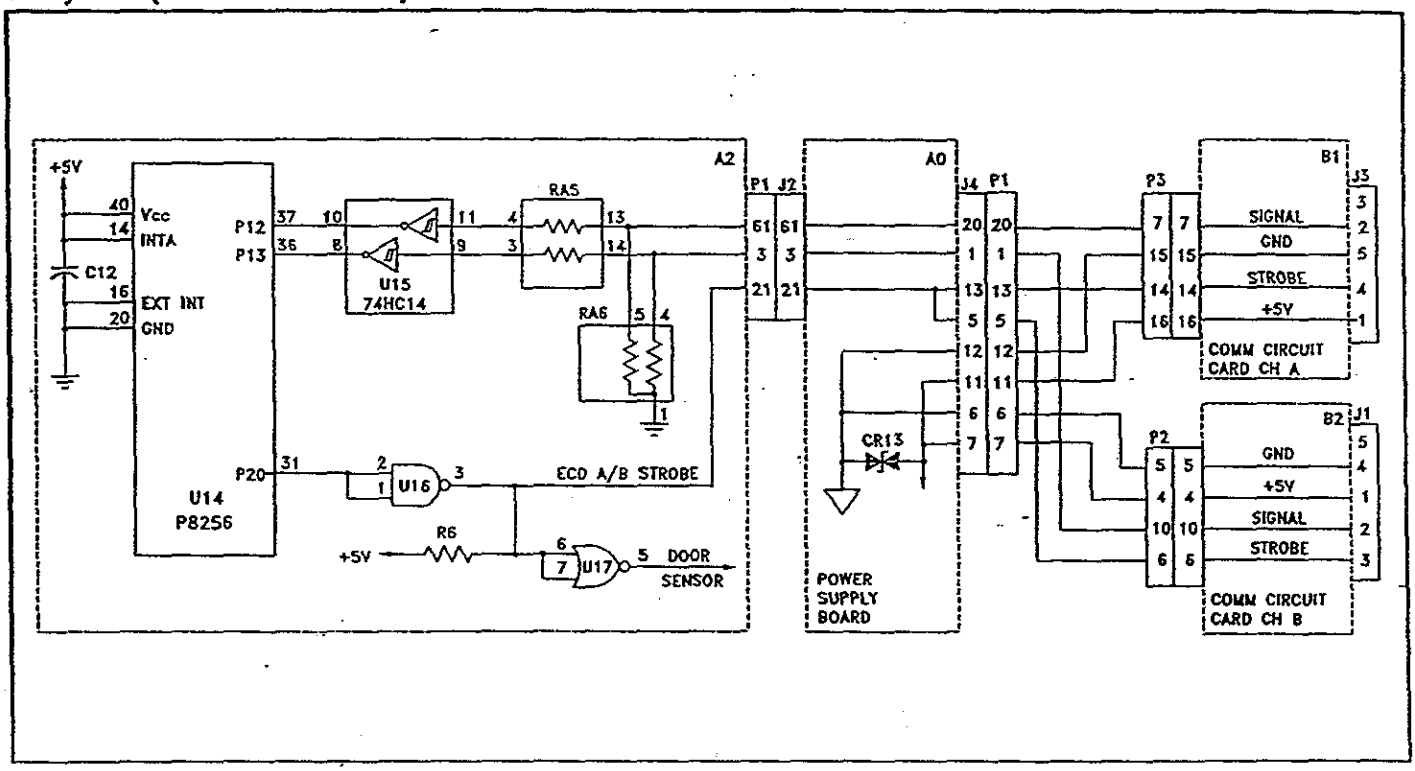


Figure 4-26. ECD Subsystem - Functional Schematic

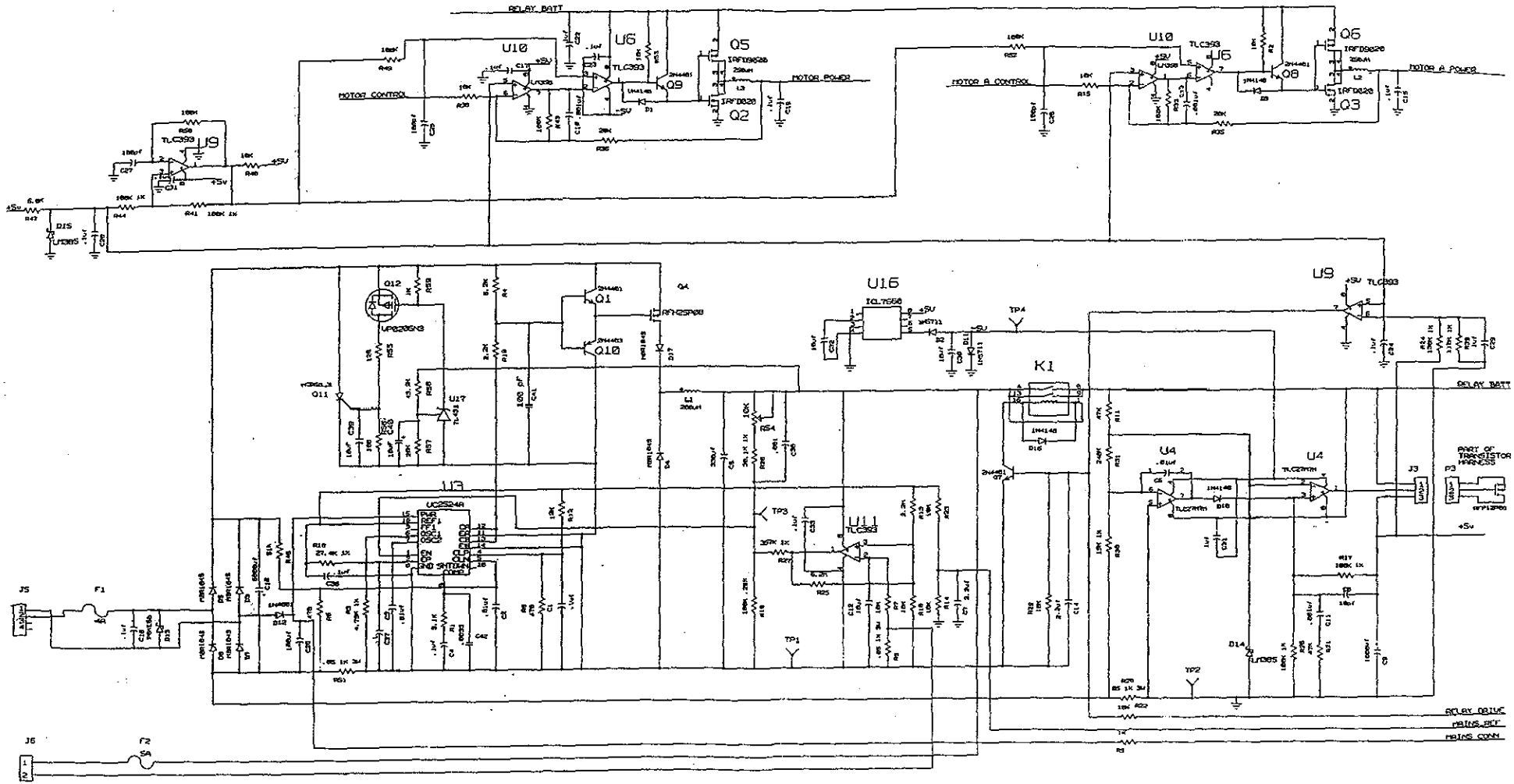


Figure 4-27. Power Supply CCA Schematic
P/N 1320-5043 (Sheet 1 of 2) [v3.xx]

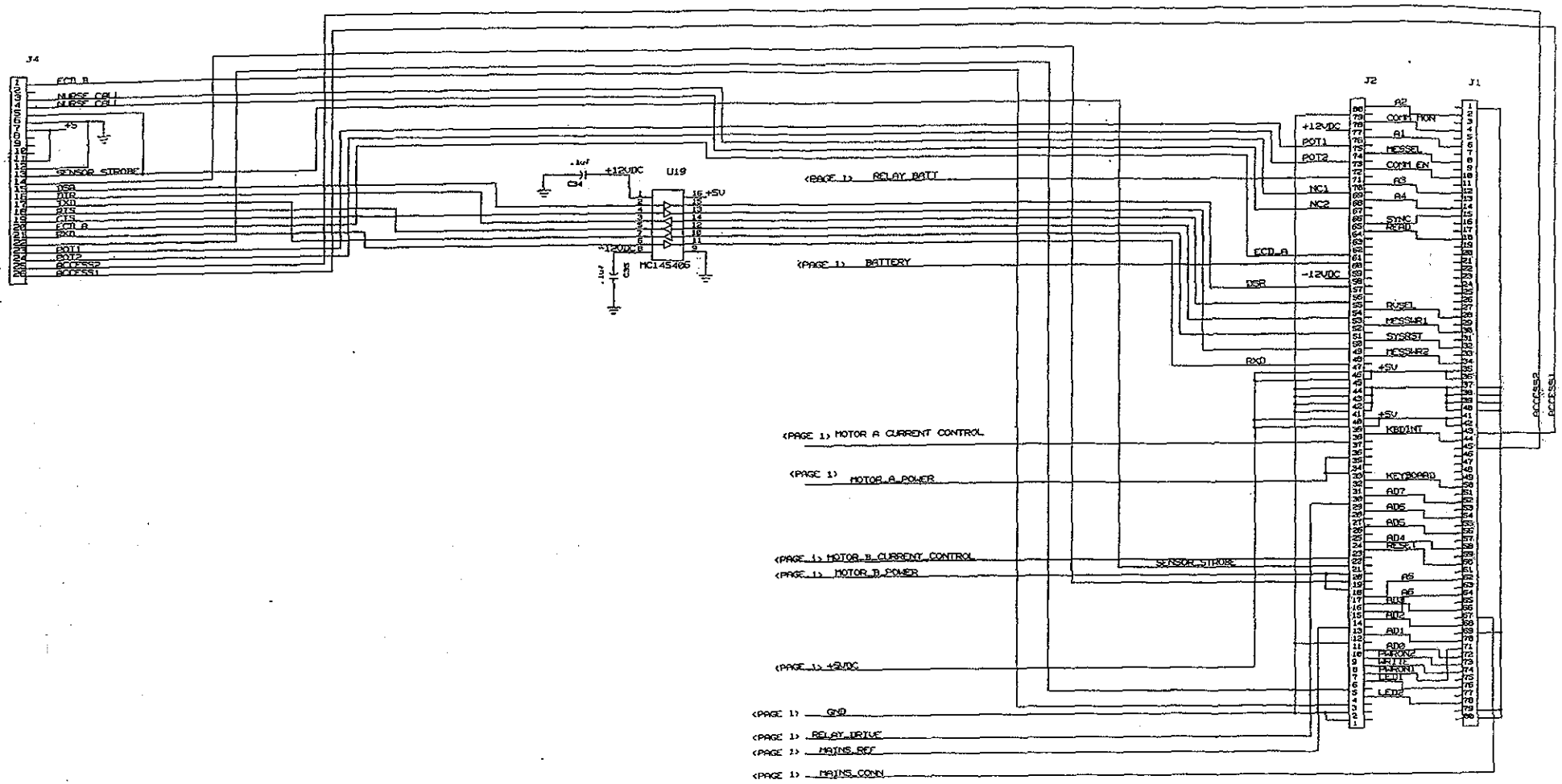


Figure 4-27. Power Supply CCA Schematic
P/N 1320-5043 (Sheet 2 of 2) [v3.xx]

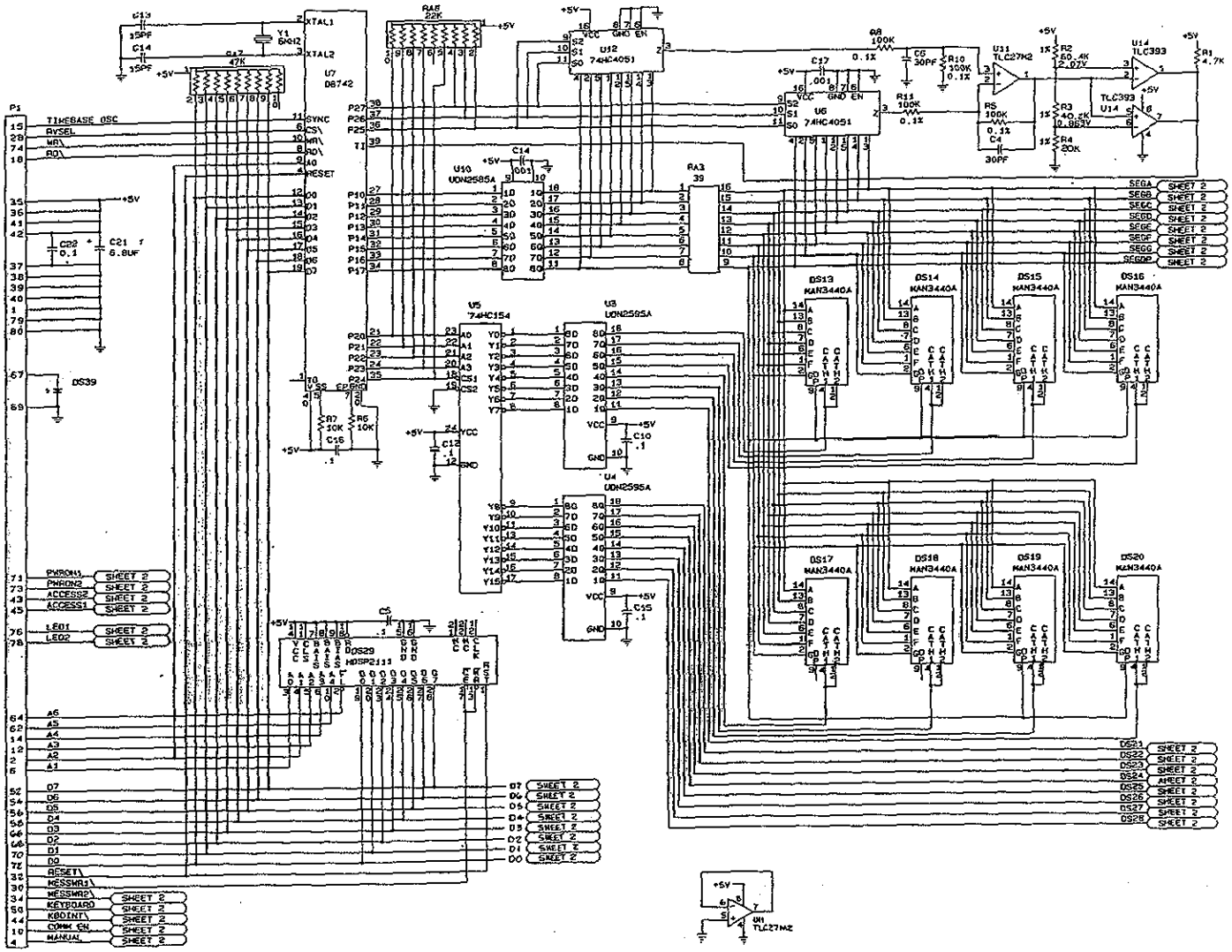


Figure 4-28. Display CCA Schematic
P/N 1320-5036 (Sheet 1 of 2) [v3.xx]

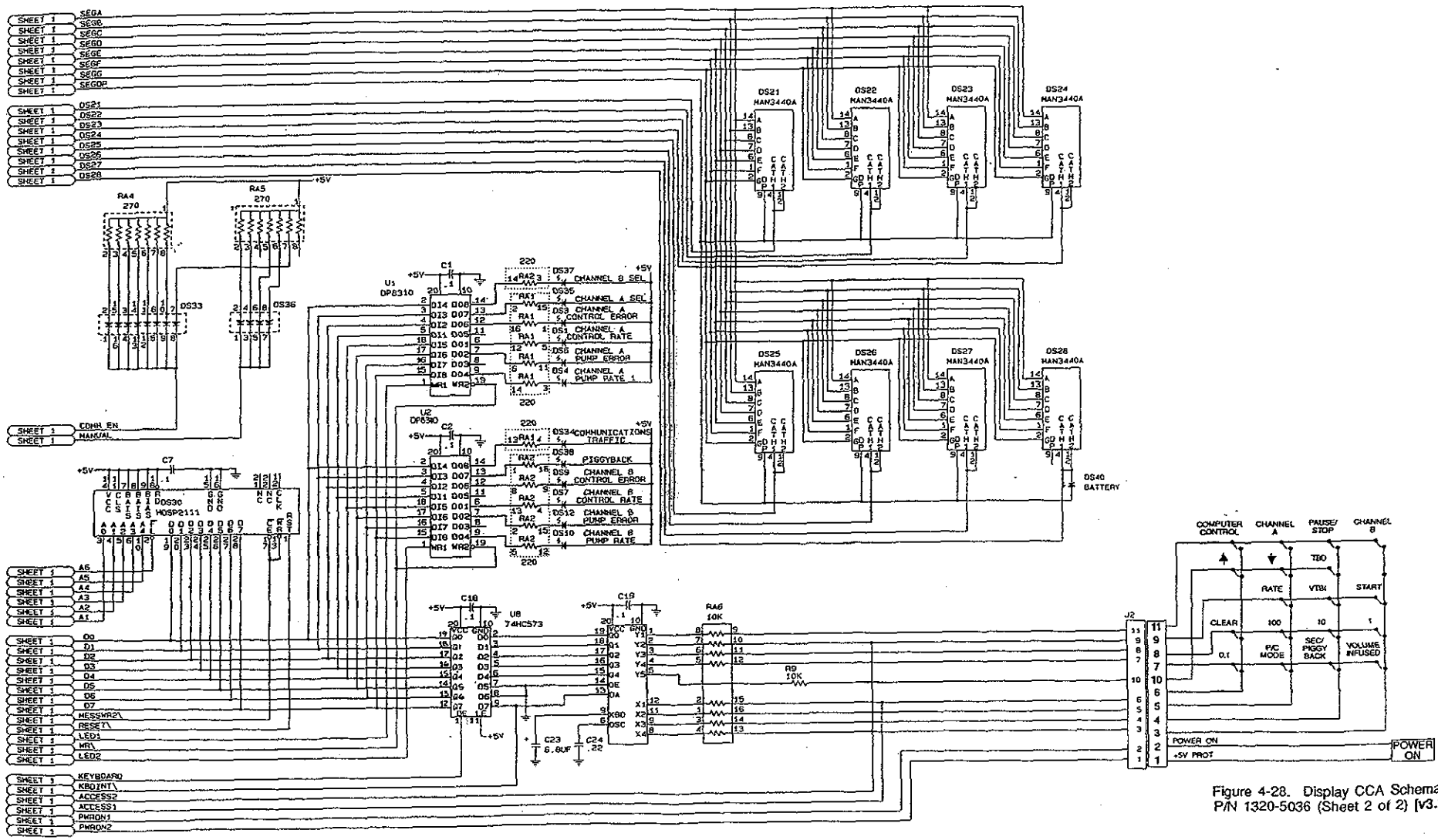


Figure 4-28. Display CCA Schematic P/N 1320-5036 (Sheet 2 of 2) [V3.XX]

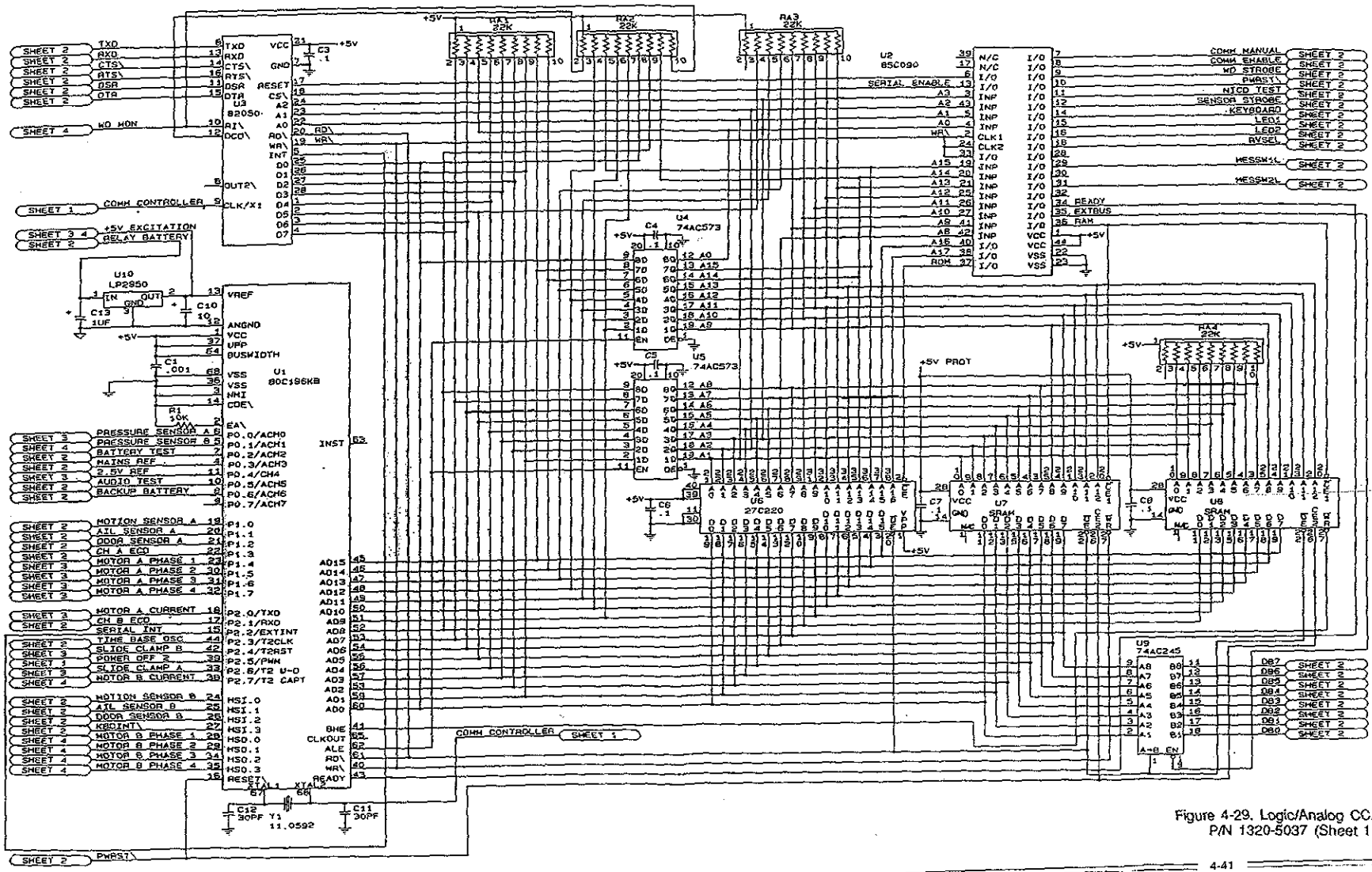


Figure 4-29. Logic/Analog CCA Schematic
P/N 1320-5037 (Sheet 1 of 4) [v3.xx]

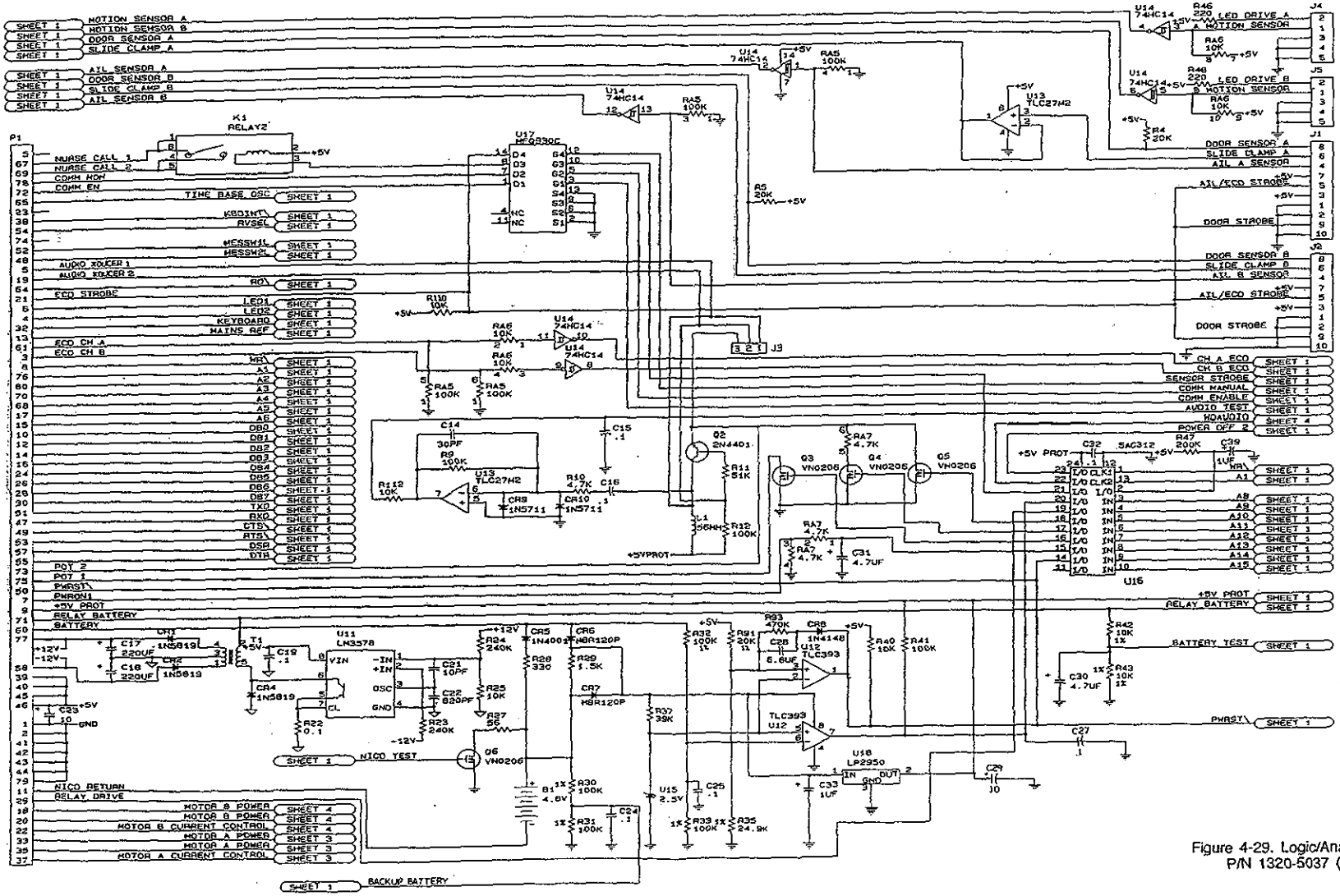


Figure 4-29. Logic/Analog CCA Schematic
P/N 1320-5037 (Sheet 2 of 4) [v3.xx]

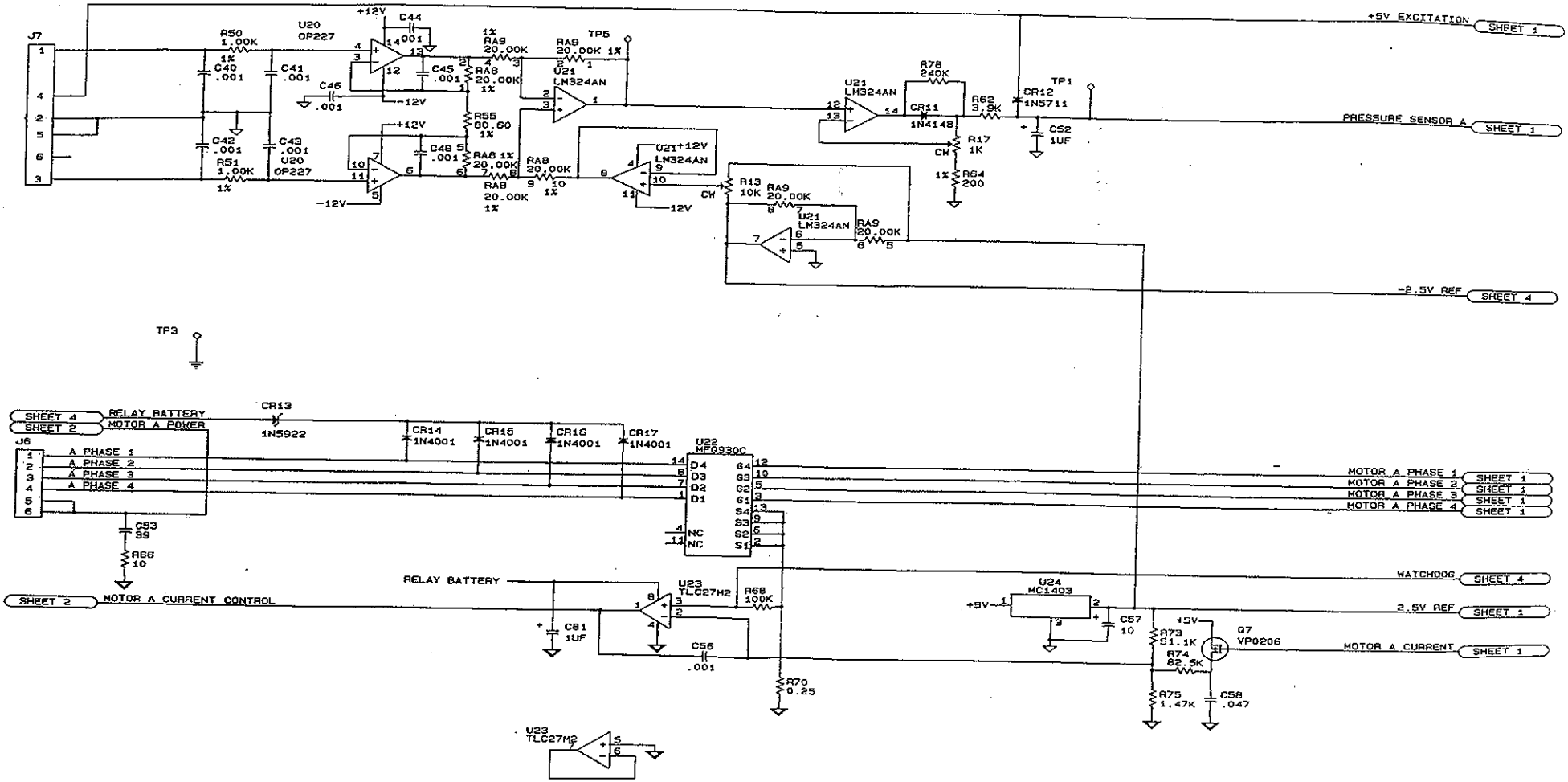


Figure 4-29. Logic/Analog CCA Schematic
P/N 1320-5037 (Sheet 3 of 4) [v3.xx]

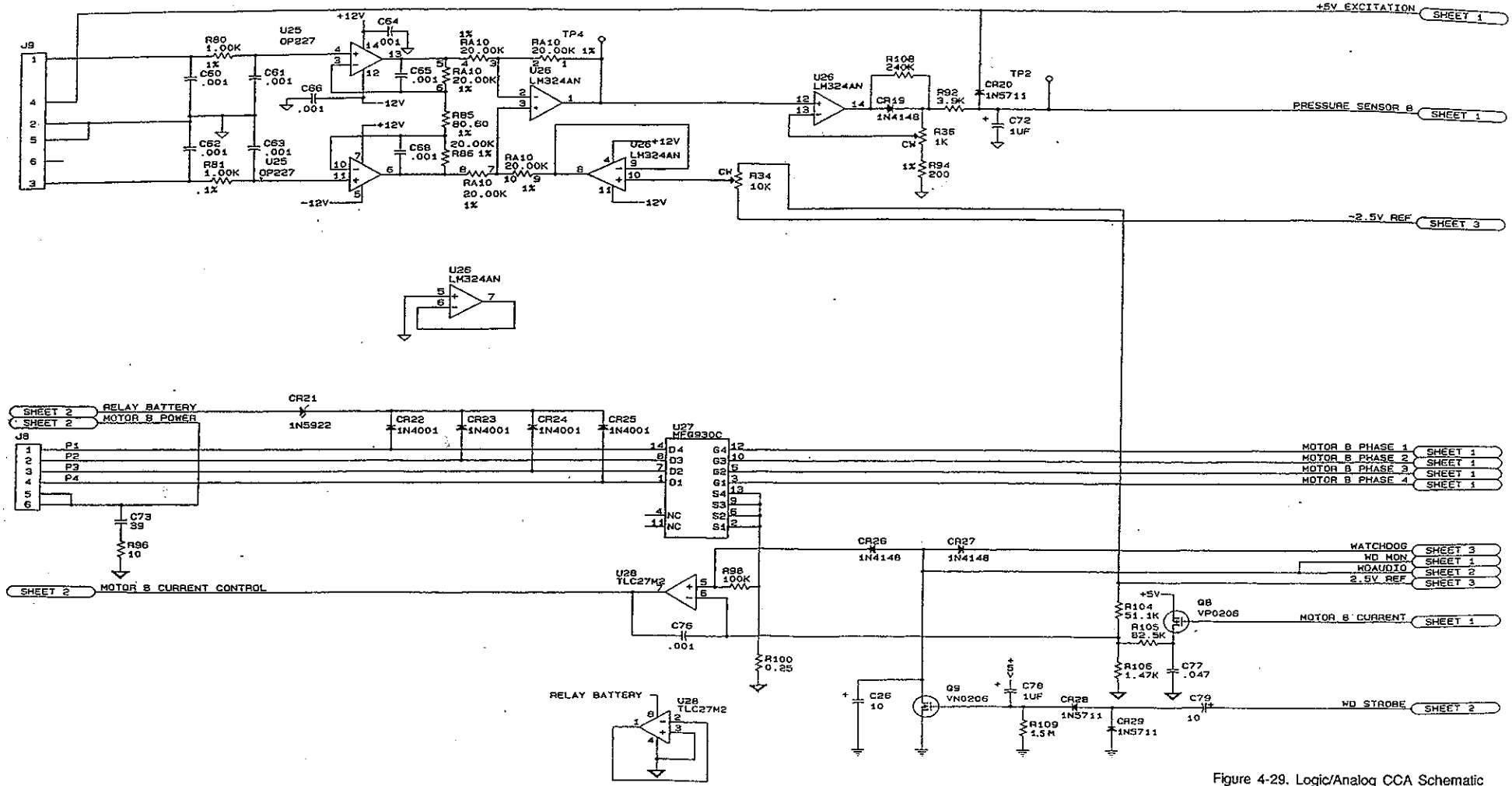


Figure 4-29. Logic/Analog CCA Schematic
P/N 1320-5037 (Sheet 4 of 4) [v3.xx]

2. Digital Voltmeter with 0.1 millivolt resolution.

3. Digital Pressure Gauge, 0-30 psi range and 0.1 psi resolution or a Mercury (Hg) manometer.

4. Stopwatch.

5. Maintenance Plug (**PC-2s with software V2.13 only**).

6. Regulated, stable air source adjustable to 10 ±0.1 psi.

WARNING

The following calibration procedure is performed with the instrument case open. The preferred procedure is to perform the calibration using a fully charged battery. If AC power is used, potentially lethal voltages are present in the rear case assembly. Use caution when connecting meter leads to the Analog PC Board.

7.3.1.2 Calibration Procedures

1. Separate the case (see Section 5.5.1).

2. If the batteries are not fully charged, connect the AC power cord.

3. Install the Maintenance Plug **(Software Release V2.13)** or press and hold the COMPUTER CONTROL/MONITOR switch (Software Release V2.33 and Subsequent).

4. Press the POWER ON control.

5. The instrument will initialize in the Maintenance Mode. Note and record the installed software version that is scrolled on the Operator Information display.

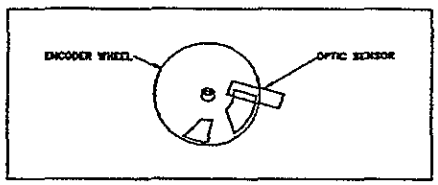
NOTE

The front case must be in the Upright position when this calibration procedure is performed. DO NOT put any pressure on the pumping chamber access door during the calibration process.

<u>Software Release V2.13</u>

6. Attach the voltmeter Ground lead (-) to TP#3 on the Analog Board (see figure 6-9) and the positive (+) lead to pin #1 on U4 (for channel A) or pin #1 on U5 (for channel B).

7. Rotate the pumping mechanism encoder wheel for the channel being calibrated to the position shown:



CAUTION

Observe the special handling and installation instructions provided with the calibrated tubing. Ensure the alignment index mark on the tubing's upper fitment is visible when installed. Any distortion of the silicon tubing will affect the voltage index (VI) values. Store the calibrated disposable in the protective cover when not in use.

8. Install the calibrated disposable in the pumping chamber of the channel to be calibrated, close the door and wait 30 seconds. Ensure distal end is vented to ambient pressure.

9. Adjust the ZERO potentiometer (R13 for channel A or R34 for channel B) to give an output voltage of 0 ±5.0 millivolts. Ignore any voltage drift after the potentiometer is correctly set.

10. Connect the positive (+) voltmeter lead to TP#1 (for channel A) or TP #2 (for channel B).

11. Apply and maintain 10.0 ±0.1 psi to the distal end of the calibration disposable, then wait a minimum of 15 seconds.

12. Adjust the SPAN potentiometer (R17 for channel A or R36 for channel B) until the voltage output is equal to the differential voltage for the calibrated disposable (HIGH minus LOW Reference voltage for your instrument's installed software version, i.e. V2.13 - 3.0 volts).

13. Adjust the ZERO potentiometer (R13 for channel A or R33 for channel B) until the voltage is equal to the HIGH Reference voltage (±0.01 volts) for the installed software version.

14. Release the pressure, ensuring the distal end is vented to ambient pressure.

15. At 30 ±5 seconds, read the output voltage. **This voltage must be equal to the LOW Reference voltage (±0.1 volts) provided with the calibrated disposable, if it is not repeat steps 7 and 9 through 15.**

16. Press the PAUSE/STOP control to power down the instrument.

WARNING

The Maintenance Plug must be removed prior to returning the instrument to service for patient care.

17. Remove the Maintenance Plug.

18. Perform a Comprehensive Operational Performance Test (See Section 7.4).

Software Release V2.33 and Subsequent

6. Actuate the COMPUTER CONTROL/ MONITOR switch to select the Motor Homing Test.

7. Press START, then use the Data Input Controls to select Motor Step 150 for the channel to be calibrated.

8. Press START. (Encoder wheel position should match figure shown in V2.13 procedure).

9. Attach the DVM positive (+) lead to pin #1 of U4 (for channel A) or pin #1 of U5 (for channel B) and the ground (-) lead to TP#3 on the Analog Board.

10. Actuate the COMPUTER CONTROL/MONITOR switch to select A/D Voltage Test, then press START. "A strain" will appear on the Operator Information display (press PAUSE/STOP control once to select "B strain").

CAUTION

Observe the special handling and installation instructions provided with the calibrated tubing. Ensure the alignment index mark on the tubing upper fitment is visible when installed. Any distortion of the silicon tubing will affect the voltage index (VI) values. Store the calibrated disposable in the protective cover when not in use.

11. Install the calibrated disposable in the pumping chamber, close the door and wait 20 seconds. Ensure distal end is vented to ambient pressure.

12. Adjust the ZERO potentiometer (R1 3 for channel A or R34 for channel B) to give a stable output of 0 ±3.0 mV. Following adjustment, disconnect the DVM.

13. Connect the positive (+) voltmeter lead to TP#1 (for channel A) or TP#2 (for channel B).

14. Apply and maintain 10.0 ±0.1 psi to the distal end of the calibration disposable. Wait a minimum of 15 seconds before proceeding.

15. Adjust the SPAN potentiometer (R17 for channel A or R36 for channel B) until the VTBI display reads 2.50 ±0.01.

16. Adjust the ZERO potentiometer (R1 3 for channel A or R34 for channel B) until the VTBI display equals the sum of the calibrated disposable's zero pressure index VI_0 plus 2.50 ±0.01. Record the final voltage value.

17. Release the pressure, ensuring the disposable's distal end is vented to ambient pressure.

18. After 30 ±5 seconds, read the VTBI display. This reading must equal VI_0 ±0.1 V; if it does not repeat steps 7 through 17. Record the actual voltage value.

19. Open the door.

20. Ensure the VTBI reading drops to either 0.00 or 0.01.

21. Using your finger, gently press against the strain beam finger with sufficient pressure to fully deflect the strain beam; confirm the strain beam voltage in the VTBI display is between 4.90 and 5.15. **If the reading is not within this range, contact ALARIS Medical Technical Service.**

22. Press COMPUTER CONTROL/MONITOR switch, then PAUSE/STOP to power down the instrument.

23. Perform a Comprehensive Operational Performance Test (see Section 7.4).

Fractional Keypad/Series v3.xx Software

6. Actuate the COMPUTER CONTROL/MONITOR switch to select the Motor Homing Test.

7. Press START, then use the Data Input Controls to select Motor Step 150 for the channel to be calibrated.

8. Press START. (Encoder wheel position should match figure shown in V2.13 procedure).

9. Attach the DVM positive (+) lead TP5 (for channel A) or TP4 (for channel B) and the ground (-) lead to TP#3 on the Logic/Analog Board.

10. Actuate the COMPUTER CONTROL/ MONITOR switch to select A/D Voltage Test, then press START. "A strain" will appear on the Operator Information display.

11. Press the ⇧ control until "V_{REF}" appears in the Operator In-formation display. Ensure the VTBI display shows a value between 2.47 and 2.53. **If the reading is not within this range, contact ALARIS Medical Technical Service.**

12. Press the ⇧ control until "A strain" appears in the Operator Information display. (Press the ⇧ control once to select "B strain").

CAUTION

Observe the special handling and installation instructions provided with the calibrated tubing. Ensure the alignment index mark on the tubing upper fitment is visible when installed. Any distortion of the silicon tubing will affect the voltage index (VI) values. Store the calibrated disposable in the protective cover when not in use.

13. Install the calibrated disposable in the pumping chamber, close the door and wait 20 seconds. Ensure distal end is vented to ambient pressure.

14. Adjust the ZERO potentiometer (R13 for channel A or R34 for channel B) to give a stable output of 0 ±3.0 mV.

15. Connect the positive (+) voltmeter lead to TP#1 (for channel A) or TP#2 (for channel B).

16. Apply and maintain 10.0 ±0.1 psi to the distal end of the calibration disposable. Wait a minimum of 15 seconds before proceeding.

17. Adjust the SPAN potentiometer (R17 for channel A or R36 for channel B) until the VTBI display reads 2.50 ±0.01.

18. Adjust the ZERO potentiometer (R13 for channel A or R34 for channel B) until the VTBI display equals the sum of the calibrated disposable's zero pressure index VI_0 plus 2.50 ±0.01. Record the final voltage value.

19. Release the pressure, ensuring the disposable's distal end is vented to ambient pressure.

20. After 30 ±5 seconds, read the VTBI display. This reading must equal VI_0 ±0.01; if it does not repeat steps 7 through 17. Record the actual voltage value.

21. Open the door.

22. Ensure the VTBI reading drops to 0.00.

23. Using your finger, gently press against the strain beam finger with sufficient pressure to fully deflect the strain beam; confirm the strain beam voltage in the VTBI display is between 4.90 and 5.15. **If the reading is not within this range, contact ALARIS Medical Technical Service.**

24. Press COMPUTER CONTROL/MONITOR switch until "Powerdown Test" appears in the Operator Information display. Press START to power down the instrument.

25. Perform a Comprehensive Operational Performance Test (see Section 7.4).

7.4 COMPREHENSIVE OPERATIONAL PERFORMANCE TEST

The comprehensive operational performance test should be performed on any PC-2 that has been removed from service for repair or has been subjected to servicing that required the case to be opened. In the event an instrument should fail to meet specified test performance criteria, it will be necessary to troubleshoot specific areas of deficiency and perform the repairs needed to restore full operational capability prior to returning the instrument to service.

7.4.1 Electrical Inspection

The pre-operational electrical inspection includes an electrical leakage test and a ground continuity check.

CAUTION

Some of these tests are inherently hazardous. Safeguards for personnel and property should be employed when conducting such tests. Tests should only be performed by qualified personnel.

7.4.1.1 Electrical Leakage Test

Perform an electrical leakage current measurement in compliance with Underwriters Laboratories (UL) 544 for *Patient Care Equipment* or Canadian Standards Association (CSA) Standard C22.2 No. 125 for *Risk Class 2G Equipment*. Leakage currents are to be less than 100 microamperes.

220V only. Perform an electrical leakage current measurement in compliance with IEC 601-1. Leakage currents are to be less than 100 microamperes.

7.4.1.2 Electrical Ground Test

Perform an electrical ground impedance measurement in compliance with UL 544 for *Patient Care Equipment* or CSA Standard C22.2 No. 125 for *Risk Class 2G Equipment*. The impedance between the grounding pin on the power cord plug and the grounding point on the rear case should not exceed 100 milliohms.

7.4.1.3 Battery Voltage Check

Perform a battery voltage check by either entering the maintenance mode (see section 5.3 for Maintenance Mode operating procedures) and utilizing the A/D Voltage display's system battery (sys batt) test to check the battery voltage (reading will be 0.5 true voltage), or by following the instrument disassembly procedures described in Section 5.5 and connecting a voltmeter across the battery terminals. Battery voltage should read 6.5 volts ±0.3 volts. Batteries installed in instruments primarily operated on battery power should be charged for 12 hours in a non-operating condition, then unplugged and allowed to stabilize for 4 hours prior to performing voltage check. Batteries testing less than 6.2 volts should be subjected to further testing or be replaced.

7.4.1.4 Dielectric Test (Optional)

Perform a dielectric withstand test in compliance with UL 544 for *Patient Care Equipment* and/or CSA Standard C22.2 No. 125 for *Risk Class 2G Equipment*. Leakage current to be <1mA at 1500 volts.

7.4.1.5 Lithium Battery Check

1. Turn instrument off and unplug AC power cord from outlet.
2. Open the instrument case (see Section 5.5.1).
3. Connect a digital voltmeter between ground (TP3) and V_{RAM} (U8, pin 16) on the Analog Board.
4. Disconnect the battery harness at J6 on the Power Supply Board.
5. After the audio initiates, allow the voltmeter display to stabilize (≈30 seconds), then note the meter reading. Reading should be >2.25 Volts.
6. Reconnect the battery harness and press the POWER ON control to silence the audio.
7. If the voltage reading is ≤2.25 Volts, the lithium battery (B1) on the Logic Board should be replaced.

7.4.2 Qualitative Operational Performance Test

7.4.2.1 Abbreviated Operational Performance Test

The abbreviated qualitative operational performance test will check the PC-2's keypad, audio control, displays and indicators; instrument operation in the Pump and Controller modes including those audio and visual alerts associated with normal instrument operation and the instrument power down sequence. Perform the abbreviated qualitative operational performance test in accordance with the procedures described in Section 5.3.1.

7.4.3 Quantitative Operational Performance Test

The following operational performance tests are designed to ensure the PC-2 is functioning in accordance with design specifications. Test procedures are provided to evaluate specific areas of instrument performance.

7.4.3.1 Equipment Requirements

1. Universal test station: (see Figure 7-1).
   - Selector valve manifold
   - 10 mL Volumetric burette
   - Pressure gauge, 0-60 psig, accurate within 2.0% or better
   - 36" (1 m) view tube (macrobore tubing on yard/meter stick).
2. Gas tight syringe, 100 μL capacity.
3. Stopwatch with minimum resolution of 1 second.
4. Vented bottle or bag of Normal Saline.
5. GEMINI Non-vented Administration set with 2 injection sites.
6. Waste fluid catch basin.
7. Nurse Call test lamp.
8. Maintenance Plug (**Software Release V2.13**).
9. Test Data Sheet (see Figure 7-3).

7.4.3.2 Test Procedures

The following test procedures are presented in a sequence that will allow the required test protocols to be accomplished accurately and in an expeditious and efficient manner. Tests are identical for channel B; upon completion of channel A testing, repeat for channel B.

TEST SETUP

1. Spike a vented bottle or bag of Normal Saline or tap water with a GEMINI Non-vented administration set and hang on the IV solution test stand. Check to ensure the roller clamp is closed.
2. Connect the distal end of the tubing set to the input side of the stopcock manifold.
3. Set the stopcocks to allow fluid to pass through the manifold to the fluid catch basin.
4. Flood the drip chamber, open the roller clamp, prime the set then close the second stopcock.
5. Adjust the height of the solution container to provide a measured head height of 24" (61 cm) i.e., 24" of vertical displacement between the strain beam and the fluid level in the container.
6. Install the tubing set in channel A of the PC-2; close and latch the access door.
7. Ensure the tubing segment between the stopcock manifold and the pressure gauge is primed.
8. Press POWER ON control and ACCESS CHANNEL A.
9. Select CONTROLLER mode, set RATE to 125 mL/hr and set VTBI to 100 mL.

LOW-FLOW HEIGHT TEST

1. Turn stopcock #3 to direct the pump output to the 36" view tube only. Ensure the 18" mark on the view tube is level with the fluid in the solution container.
2. Press START and observe:
   - Fluid column rises in the view tube
   - Pumping mechanism stops
   - Audio Advisory sounds
   - "LOW FLOW" advisory scrolls for 1 minute
   - After 1 minute audio alert changes to Alarm and "OCCLUDED" scrolls continuously.
3. Record the height of the fluid column in the view tube on the data sheet (reading must be between 6 and 30 inches).
4. Silence alarm, press ACCESS CHANNEL A, then press PAUSE/STOP once.
5. Turn stopcock #3 to drain the fluid column to waste; drain to the 0 graduation, then turn the stopcock to the bypass position.

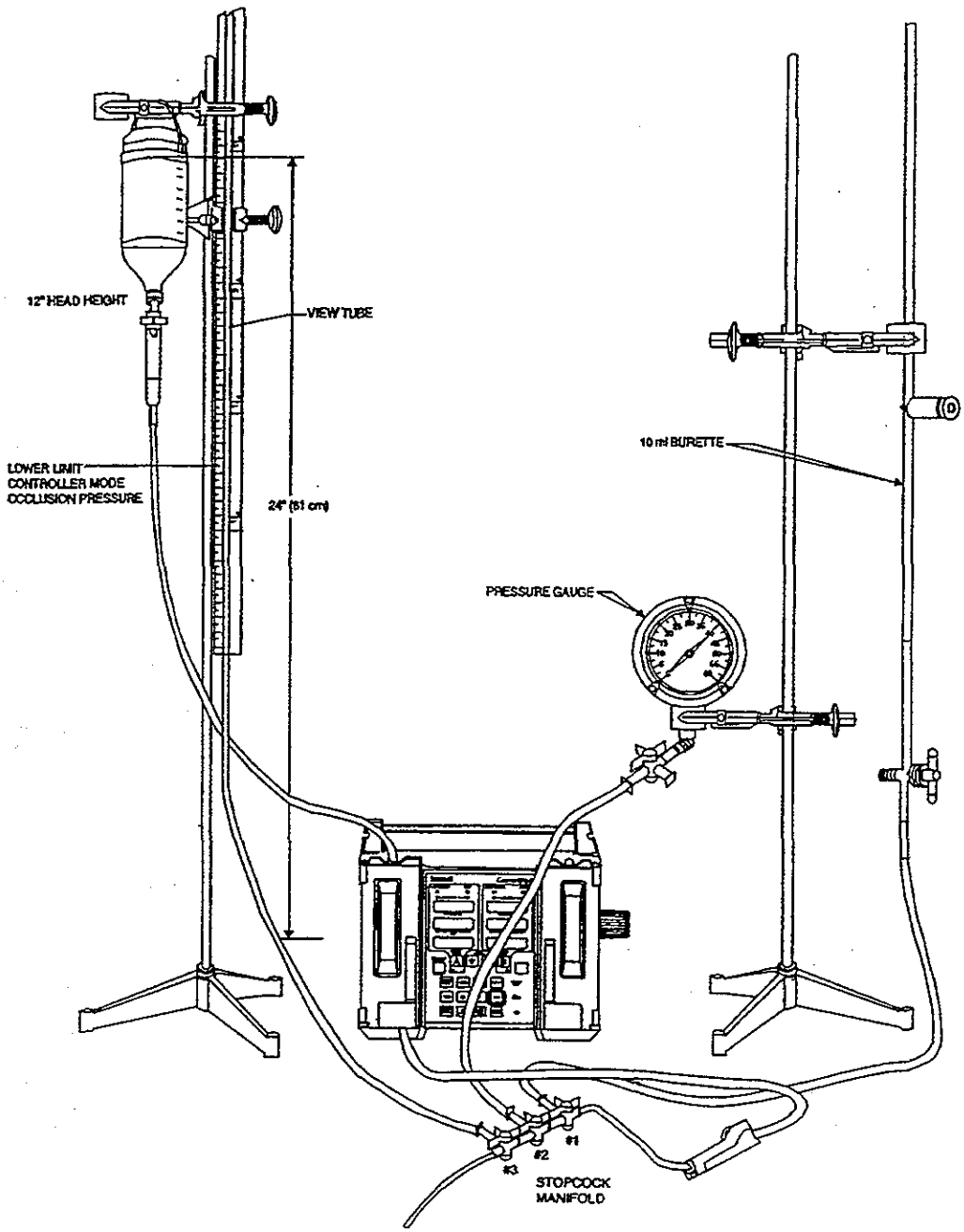


Figure 7-1. Universal Test Station Setup

OUTPUT PRESSURE TEST

1. Turn stopcock #2 to direct pump output to the pressure gauge.
2. Select PUMP mode.
3. Press START and observe:
   - Pumping mechanism stops
   - Audio Alarm sounds
   - "OCCLUDED-PATIENT SIDE" scrolls continuously.
4. Record pressure gauge reading on the data sheet immediately following alarm (reading must be between 8 and 12 psi).
5. Silence alarm, press ACCESS CHANNEL A, then press PAUSE/STOP once.
6. Turn stopcock #2 to the bypass position momentarily to relieve the pressure and then turn back to the pressure gauge position.

MAXIMUM PRESSURE TEST

1. Initialize instrument in the Maintenance Mode.
2. Press COMPUTER CONTROL/MONITOR switch to select "pump test".
3. Press START control twice.
4. Verify rate set to 125 mL/hr and VTBI >25 mL.
5. Press START control and allow the pump to operate for at least 30 seconds and wait until the peak pressure stabilizes.
6. Record the highest pressure reading obtained. **Resultant pressure must be >17 psi.**
7. Press Channel A and then press PAUSE/STOP control twice to power down the instrument.
8. Turn the Test Station stopcock #2 to the bypass position.

VOLUME/RATE/TIME TEST

Software Release V2.13

1. Perform Motor Homing Test on channel to be tested (see Section 5.3.2).

Software Release V2.33 and Subsequent

1. Home channel by opening appropriate pumping chamber access door.
2. Turn stopcock #1 to direct fluid flow to the 10mL burette.
3. Press START to fill the burette to the 10mL line, then press ACCESS CHANNEL A and PAUSE/STOP once.
4. Press VOLUME INFUSED followed by CLEAR to reset the Volume Infused register to "0".
5. Set VTBI to 5 mL and verify the RATE is set to 125 ml.
6. Press START and start the stopwatch simultaneously.
7. When audio Advisory sounds and "INFUSION COMPLETE-KVO" scrolls, immediately stop the stopwatch and press ACCESS CHANNEL A followed by PAUSE/STOP twice.

NOTE

Failure to stop the pump immediately will induce a volume accuracy error into the test.

8. Read the fluid level in the burette.
9. Record the volume delivered (10 mL minus fluid level from step #7) and elapsed time on the data sheet (Volume delivered must be between 4.7 and 5.3 mL and elapsed time must be within 2:16 and 2:31 min:sec limits).
10. Turn stopcock #1 to drain the fluid in the burette down to the 10mL line.

NURSE CALL INTERFACE AND MAINTENANCE MODE FUNCTIONAL TEST

NOTE

The following procedures are not channel dependent and need only be performed once.

1. Remove all disposables from the instrument.
2. Install the communications emulator plug in the RS-232-C Data Port.

3. Install the Maintenance Plug in the Nurse Call/Maintenance Plug connector.
4. Press POWER ON.
5. Following the audio tone at the end of the initialization sequence, remove the Maintenance Plug and install the Nurse Call test light.
6. Check the Nurse Call test light is illuminated.
7. Remove the Nurse Call test light and reinstall the Maintenance Plug.
8. Perform the following Maintenance Mode test in order (refer to Section 5.3.2 for procedures):
   - Lamp test (vary audio volume during the test)
   - Keypad test
   - Error Log Display (clear log if 'newest' is displayed; 'failed' message indicates log has been cleared).
   - Serial Port test
   - Input Port Display
   - Powerdown test
9. Remove the Maintenance and Communication Emulator Plugs upon completion of testing.

BATTERY CAPACITY CHECK

Battery operation with a new, fully charged battery is ≈5 hours with the instrument operating one channel at 125 mL/hr, or ≈4 hours with both channels operating at 125 mL/hr. Under conditions of normal usage (e.g. one discharge cycle/day), the battery should retain 50% of its original capacity after one year of usage.

Usage other than that described above may result in prolonged or reduced battery life (i.e., more than one discharge/day without a complete recharge may reduce battery life).

To determine battery capacity perform the following procedure:

1. Connect the AC power cord to an AC source and allow the battery to charge for 16 hours with the instrument not operating.
2. Disconnect from the AC source and operate both channels at 125 mL/hr.
3. Record the battery-ope rated run time to the point of activation of the "HELP BATTERY" alarm.
4. If the resultant run time is less than 2 hours, consideration should be given to replacing the battery. Follow your hospital protocol for battery replacement.

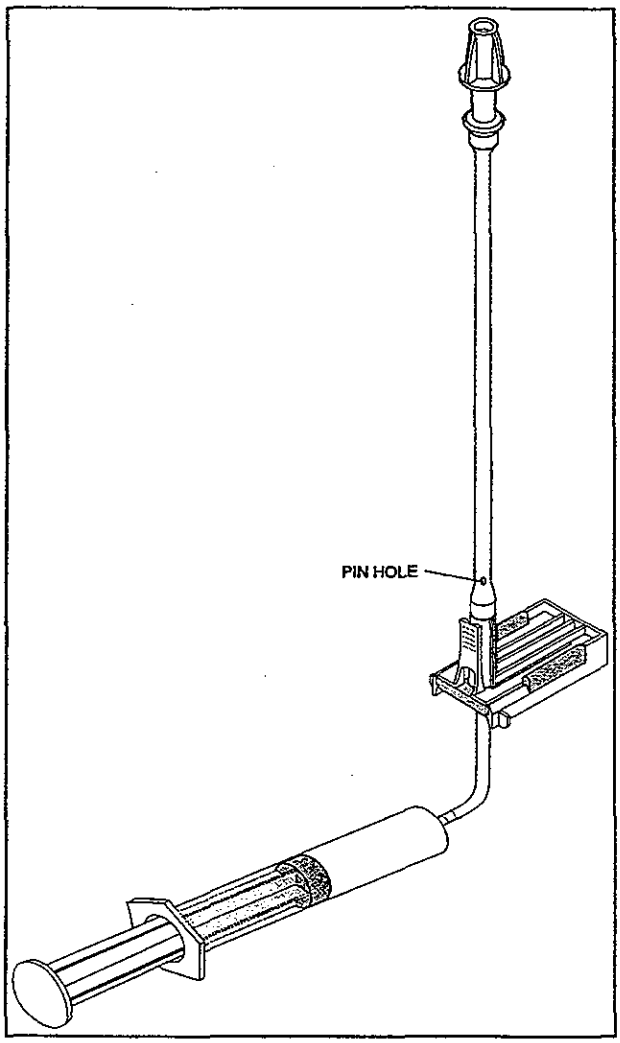


Figure 7-2. Air-in-line Simulator

PC-2 TEST DATA SHEET

Instrument Serial No._____ Software Version _____

Date _____ Technician _____

Test No.	Description	Reference	Record Result	Pass/Fail
1	Electrical Leakage Test	7.4.1.1	_____	Pass___/Fail___
2	Electrical Ground Test	7.4.1.2	_____	Pass___/Fail___
3	Battery Voltage Check	7.4.1.3	_____	Pass___/Fail___
4	Lithium Battery Check	7.4.1.5	_____	Pass___/Fail___
5	Test Procedures Initialization	7.4.3.2	_____ _____	Pass___/Fail___ Ch A Pass___/Fail___ Ch B
6	Pump Mode Operation	7.4.3.2	_____ _____	Pass___/Fail___ Ch A Pass___/Fail___ Ch B
7	Low-Flow Height Test	7.4.3.2	Fluid Height _____ _____	Pass___/Fail___ Ch A Pass___/Fail___ Ch B
8	Output Pressure Test	7.4.3.2	Pressure _____ _____	Pass___/Fail___ Ch A Pass___/Fail___ Ch B
9	Maximum Pressure Test	7.4.3.2	Pressure _____ _____	Pass___/Fail___ Ch A Pass___/Fail___ Ch B
10	Volume/Rate/Time Test	7.4.3.2	Volume _____ _____ Time _____ _____	Pass___/Fail___ Ch A Pass___/Fail___ Ch B Pass___/Fail___ Ch A Pass___/Fail___ Ch B
11	Nurse Call Test	7.4.3.2	_____	Pass___/Fail___
12	Maintenance Mode Test	7.4.3.2	_____	Pass___/Fail___
13	Battery Capacity Check	7.4.3.2	_____	Pass___/Fail___
	PC-2 OPTIONAL TESTS **These tests are to be performed at the discretion of the repairing facility**			
1	Dielectric Test	7.4.1.3	_____	Pass___/Fail___
2	Maintenance/Diagnostic Mode Test	5.3	_____	Pass___/Fail___
3	ECD Tests	3.3.1.3	_____	Pass___/Fail___

Figure 7-3. PC-2 Test Data Sheet

WARRANTY

ALARIS Medical Systems™, Inc. (hereinafter referred to as "ALARIS Medical") warrants that:

a. Each new IMED GEMINI PC-2® volumetric Infusion Pump/Controller, excluding the battery, is free from defects in material and workmanship under normal use and service for a period of one (1) year from the date of delivery by ALARIS Medical to the original purchaser.
b. The battery and each new accessory are free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by ALARIS Medical to the original purchaser.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with ALARIS Medical headquarters (San Diego, CA) to determine the appropriate repair facility. Except as provided otherwise in this warranty, repair or replacement will be carried out at ALARIS Medical's expense. The product requiring service should be returned promptly, properly packaged and postage prepaid by purchaser. Loss or damage in return shipment to the repair facility shall be at purchaser's risk.

In no event shall ALARIS Medical be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any ALARIS Medical product. This warranty shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and ALARIS Medical shall not be responsible for, any loss or damage arising in connection with the purchase or use of any ALARIS Medical product which has been:

(a) repaired by anyone other than an authorized ALARIS Medical service representative:
(b) altered in any way so as to affect, in ALARIS Medical's judgement, the product's stability or reliability:
(c) subjected to misuse or negligence or accident, or which has had the product's serial or lot number altered, effaced or removed:

or

(d) improperly maintained or used in any manner other than in accordance with the written instructions furnished by ALARIS Medical.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of ALARIS Medical, and ALARIS Medical does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of ALARIS Medical any other liability in connection with the sale or use of ALARIS Medical products.

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See packing inserts for international warranty, if applicable.

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Service Bulletin 412B

P/N 143287A

Service Bulletins are supplements to ALARIS Medical Technical Service/Maintenance Manuals.

Models Affected: Gemini® Volumetric Infusion Pump/Controller; 1310/1311, 1320/1321, 1325/1326, 1340/1341
Date: May 1998
Subject: Level of Testing Guidelines

☞ *This supersedes Service Bulletin 412A, to provide the testing requirements for occlusion detection based on the mode of operation in which the instrument is set, and reflect various updates to the Level of Testing Guidelines table.*

Purpose

The purpose of this bulletin is to provide Biomedical Technicians the following:

- A Level of Testing Guidelines table, to replace all existing references to testing required after repair (*reference Maintenance chapter of maintenance manual for each Gemini model*).
- Updated maintenance manual part number information (*reference Preface section of maintenance manual for each Gemini model*).

Explanation

The tests currently specified in each maintenance manual as being required after repair may not reflect current testing requirements or recommendations. To help provide the most current minimum test requirements, a Level of Testing Guidelines table has been provided.

The part number referenced in the Preface section of each maintenance manual, as the part number to be used when ordering a manual, is no longer current.

References

Gemini PC-1 Maintenance Manual (*dated September 1, 1995, and later*)
Gemini PC-2 Maintenance Manual (*dated April 1, 1996*)
Gemini PC-2TX Maintenance Manual (*dated May 1, 1996*)
Gemini PC-4 Maintenance Manual (*dated November 1, 1995*)

Parts and Tools Required

As specified in the appropriate sections of the service manual.

Recommended Action

Add this Service Bulletin to your Gemini PC-1, PC-2, PC-2TX, or PC-4 Maintenance Manual references (*as applicable, see above References*), as a supplement to the Maintenance chapter.

1. To ensure that all appropriate supplemental documents (such as this service bulletin) are included when receiving a new maintenance manual, use the following part numbers when ordering a manual.

Model	P/N
1310/1 (PC-1)	142034
1320/1 (PC-2)	141880
1325/6 (PC-2TX)	141881
1340/1 (PC-4)	141882

2. Any instrument repair or disassembly/reassembly must be followed by testing, determined by the level of the repair/disassembly. Use the following Level of Testing Guidelines, Table 5-5, in place of the test requirements specified in the Maintenance chapter of the maintenance manual.

Table 5-5 Notes:

- The tests identified as "required" are for all Gemini models, unless otherwise noted (next to repair item description).
- The required tests can be found in the *Maintenance* chapter of the applicable maintenance manual, with the exception of the following test, which can be found in the noted section of the *Preparation for Use* chapter.

Test	Section	Models
Display Test	2.3.3.2: Initial Setup, step 4	1325/6, 1340/1

- To test for occlusion detection, perform one of the following steps, as applicable to the mode of operation in which the instrument is set. If the instrument is:

  a. Locked in the "pump" mode:
  Perform the "Output Pressure Test".

  b. Locked in the "controller" mode:
  Perform the "Low-Flow Head Height Test", and the "Output Pressure Test" until the point at which the instrument alarms "OCCLUDED-FLUID SIDE".

  c. Not locked in either the "pump" or "controller" mode:
  Perform the "Low-Flow Head Height Test" and the "Output Pressure Test".

Table 5-5 Level of Testing Guidelines

Repair/Replacement/Adjustment of ↓ / Tests to Perform ➡ (● = Required)	Electrical Leakage Test	Electrical Ground Test	Occlusion Detection	Pump Pressure/ Maximum Pressure Test	Volume/Rate/Time Test	Keypad Test	Lamp Test	Display Test	Strain Beam Calibration	A/D Voltage Display
No Fault Found	●	●	●	●						
Air-in-Line Assembly	●	●	●	●	●					
Analog Board Assembly: 1320/1	●	●	●	●					●	
Anchor Bracket	●	●	●	●						
AC Receptacle Assembly/Power Entry Module	●	●	●	●						●
Audio Oscillator	●	●	●	●						
Battery	●	●	●	●						
Display Board Assembly: 1310/1, 1320/1	●	●	●	●		●	●			
1325/6, 1340/1	●	●	●	●				●		
Door/Door Assembly	●	●	●	●	●				●	
Front Case/Assembly Parts	●	●	●	●	●				●	
Handle	●	●	●	●						
Harness Assembly (any)	●	●	●	●						
Keypad Assembly	●	●	●	●		●				
Logic Board Assembly: 1310/1, 1320/1	●	●	●	●					●	
1325/6, 1340/1	●	●	●	●						
Motor Controller Board Assembly: 1325/6, 1340/1	●	●	●	●					●	
Pole Clamp Assembly	●	●	●	●						●
Power Supply Board Assembly	●	●	●	●						●
Pumping Mechanism Assembly/Parts	●	●	●	●	●					
Rear Case/Assembly Parts	●	●	●	●						●
Strain Beam/Transducer Assembly	●	●	●	●	●				●	
Transformer Assembly	●	●	●	●						●

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Service Bulletin 419

P/N 142259A

Service Bulletins are supplements to ALARIS Medical's Technical Service/Maintenance Manuals.

Model Affected: Gemini® Volumetric Infusion Pump/Controller; PC-2CE
Date: October 1997
Subject: Release of Model 1321, PC-2CE

Purpose

The purpose of this bulletin is to provide Biomedical Technicians the following:

- information related to the release of Model 1321, PC-2CE, and
- updated part number information.

This is *reference information only* and is not intended to suggest a need for component changes.

Explanation

A 220V instrument having Version 3.44 software is referred to as a PC-2CE, Model 1320. The software has been updated to Version 3.45, and an instrument having this version software is referred to as a PC-2CE, Model 1321. The only difference between a Model 1320 instrument and Model 1321 instrument is the software. Version 3.45 software displays "517mmHg" (instead of "10psi") when operating in the 10psi mode and the selected language is not English.

References

PC-2 Maintenance Manual (*dated April 1, 1996, or later*)

Parts and Tools Required

Reference the appropriate sections of the maintenance manual, if servicing becomes necessary.

Recommended Action

Include the following information, as a supplement to the Illustrated Parts Breakdown chapter of the maintenance manual, when replacing or repairing a PC-2CE analog/logic board assembly in an instrument having Version 3.44 or 3.45 software (Model 1320 or Model 1321), and when ordering a PC-2CE Operator's Manual (now being identified as Directions For Use).

NOTE: The software version is displayed when the instrument is powered up (scrolls once across the display) and when entering the Setup Mode.

Interchangeability Information

Operator's Manual:

The Operator's Manual used with a Version 3.44 instrument is different than the Directions For Use (DFU) used with a Version 3.45 (Model 1321) instrument. A new DFU is provided with each software upgrade kit, but is not provided as part of the analog/logic board replacement kit. (*See following part number information.*)

NOTE: When ordering a replacement analog/logic board assembly for a Version 3.44 instrument, it may be necessary to also order a DFU for a Version 3.45 (Model 1321) instrument.

Analog/Logic Board Assembly
(Models 1320 and 1321, PC-2CE)

NOTE: When ordering an analog/logic board assembly or software please specify the software version being replaced.

Ref Des	Part Number	Description	Qty.
	142267	Kit, Analog/Logic Board (Kit consists of Version 3.45 analog/logic board assembly, and Serial Number Report Instrument Upgrade Form.)	1
To replace Version 3.44 software:			
U6		Kit, Upgrade from Version 3.44 to Version 3.45 (Each kit consists of programmed analog/logic IC, Directions For Use, and Serial Number Report Instrument Upgrade Form.)	1
	142266	Australian	
	142261	English	
	142264	French	
	142262	Italian	
	142263	Spanish	
	142265	Swedish	
To replace Version 3.45 software:			
U6	142260	IC, Analog/Logic, Version 3.45	1

Literature

(Models 1320 and 1321, PC-2CE)

Part Number	Description	Qty.
	Operator's Manual, 1320 (Version 3.44)	1
20-9249-7	Australian	
20-9244-7	English	
20-9247-7	French	
20-9245-7	Italian	
20-9246-7	Spanish	
20-9248-7	Swedish	
	Directions For Use, 1321 (Version 3.45)	1
142221	Australian	
142220	English	
142222	French	
142223	Italian	
142225	Spanish	
142224	Swedish	

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Service Bulletin 427

P/N 142714A

Service Bulletins are supplements to ALARIS Medical Technical Service/Maintenance Manuals.

Models Affected: Gemini® Volumetric Infusion Pump/Controller;
1310/1311 (PC-1), 1320/1321 (PC-2), 1325/1326 (PC-2TX), 1340/1341 (PC-4)
Date: March 1998
Subject: Gemini Administration Set Loading

Purpose

The purpose of this bulletin is to provide Biomedical Technicians and instrument users additional information on the proper loading of the Gemini administration set.

Explanation

The administration set can be damaged if it is not properly loaded.

References

Gemini PC-1 Maintenance Manual (*dated September 1, 1995, and later; ordered as P/N 142034*)
Gemini PC-2 Maintenance Manual (*dated April 1, 1996; ordered as P/N 141880*)
Gemini PC-2TX Maintenance Manual (*dated May 1, 1996; ordered as P/N141881*)
Gemini PC-4 Maintenance Manual (*dated November 1, 1995; ordered as P/N 141882*)

Parts and Tools Required

Not Applicable

Recommended Action

When loading an administration set into a Model 1310/1311, 1320/1321, 1325/1326, or 1340/1341 instrument, observe the following caution.

CAUTION

To avoid damage to the pumping chamber, load and unload the upper fitment in a "vertical" orientation.

Make note of the **CAUTION** statement, or reference this bulletin, in the *Setup and Operating Procedures* section in the *Operation* chapter of the maintenance manual. The applicable steps are as follows:

Model	Applicable Step
1310/1311 (PC-1)	9 (page 3-10)
1320/1321 (PC-2)	10 (page 3-10)
1325/1326 (PC-2TX), 1340/1341 (PC-4)	8 (page 3-7)

Parts Ordering: Refer to Illustrated Parts Breakdown chapter of the Maintenance Manual
Technical Inquiries: 1-800-854-7128, 1-619-458-6003, FAX 1-619-458-7507

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Service Bulletin 441

P/N 144578A

Service Bulletins are supplements to ALARIS Medical Technical Service/Maintenance Manuals.

Model Affected: Gemini® Volumetric Infusion Pump/Controller, 1321
Date: May 1999
Subject: Model 1321CX Released

Purpose

The purpose of this bulletin is to provide Biomedical Technicians information related to the release of Model 1321CX.

Explanation

The polarity for Q9 (watchdog FET) is silk-screened on bare board P/N 1320-6068-7 the reverse of the correct polarity indicated on the schematic. The silk-screen error requires that Q9 be installed with its polarity opposite to that silk-screened on the board. Bare board P/N 1320-6068-7 is used in the build of logic board assemblies installed in 220V instruments. Model 1321CX instruments are built using a logic board that has Q9 correctly installed. Model 1321AX, 1321BX, and 220V 1320 instruments are to have the correct orientation of Q9 verified when the instrument is being serviced.

References

PC-2 (Model 1320/1321) Technical Service/Maintenance Manual
(*identified as P/N 1320-9243-00 or 143624, ordered as P/N 141880*)

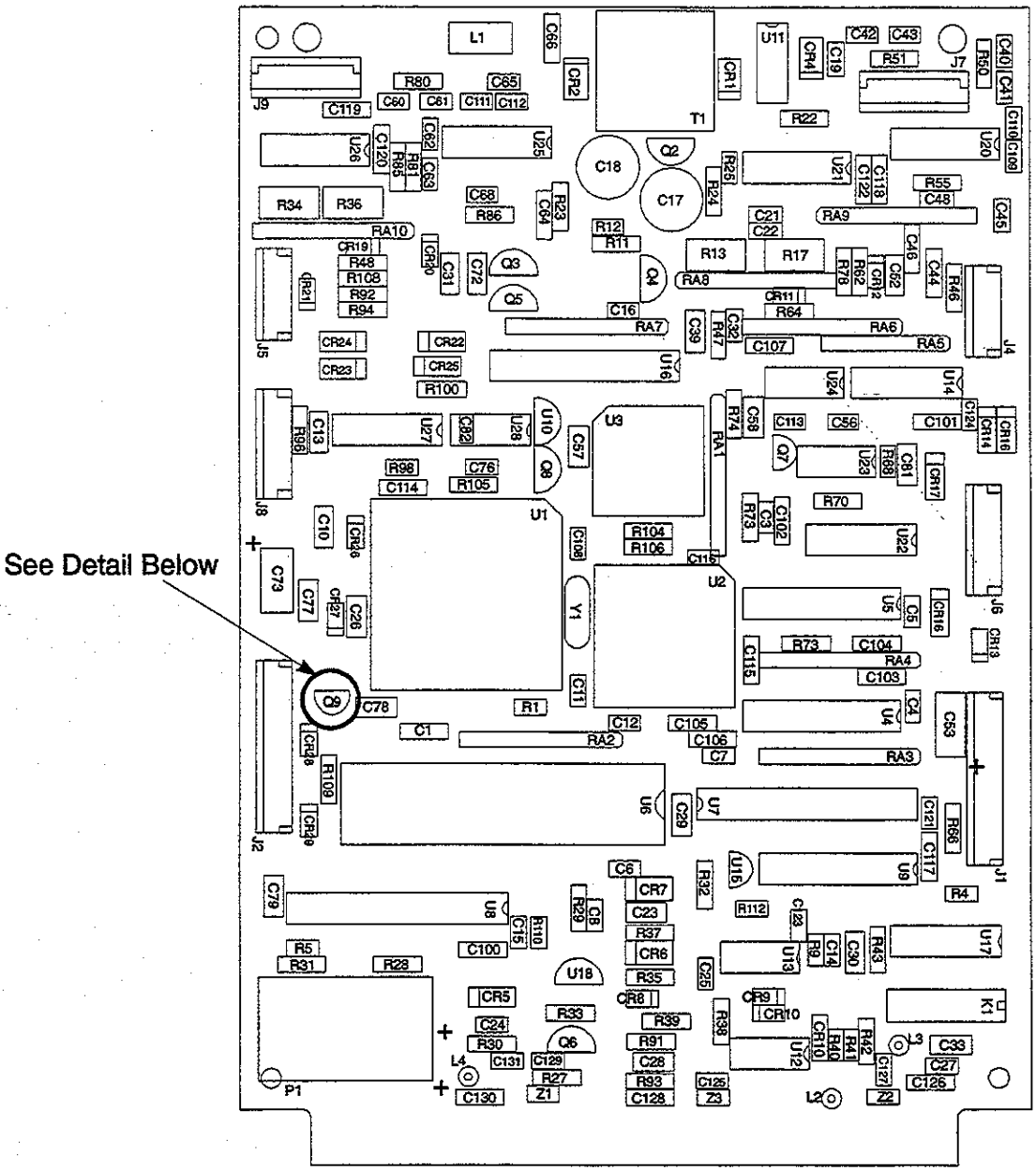
Parts and Tools Required

Reference the appropriate sections of the service/maintenance manual if servicing becomes necessary.

Recommended Action

When servicing/repairing a logic board assembly in a 220V instrument, be aware that Q9, on bare board P/N 20-6068-7, must be installed with its polarity opposite to that silk-screened on the board.

Figure 1 – Logic Board Assembly using bare board P/N 20-6068-7. (This illustration is not part of the current service manual.)



DETAIL

Existing Silk-Screen
(not correct)

Correct Q9 Orientation

ALARIS™
Medical Systems

10221 Wateridge Circle
San Diego, CA 92121, U.S.A.
P.O. Box 85335, San Diego, CA 92186-5335

Service Bulletin 462

P/N 145440A

Service Bulletins are supplements to ALARIS Medical Technical Service/Maintenance Manuals.

Model Affected: Gemini® Volumetric Infusion Pump/Controller, 1320/1321
Date: December 1999
Subject: Display Board and I/O Harness/Board Assemblies

Purpose

The purpose of this bulletin is to provide Biomedical Technicians the following:

- Current Display Board Assembly and I/O (Communication) Harness/Board Assembly parts breakdown and schematic information.
- Updated Final Assembly, Front Case Assembly, and Rear Case Assembly parts lists.

This is *reference information only* and is not intended to suggest a need for component changes.

Explanation

The display board and I/O (communication) harness/board assemblies previously used only for the Model 1321 (220V PC-2) are now also being used for the Model 1320 (110V PC-2). Other part numbers listed in the maintenance manual for the Final Assembly, Front Case Assembly, and Rear Case Assembly have been updated since the manual's initial release.

References

PC-2 (Model 1320/1321) Technical Service/Maintenance Manual
(*identified as P/N 1320-9243-00 or 143624; ordered as P/N 141880*)

Parts and Tools Required

Reference the appropriate sections of the service/maintenance manual if servicing becomes necessary.

Recommended Action

Include the following parts breakdown information as part of the maintenance manual references.

Final Assembly, 110V/220V

(Replaces corresponding information in Illustrated Parts Breakdown chapter of maintenance manual.)

Item	Part Number	Description	Qty.
40	20-2133-7	Handle	1
50	20-2149-7	Insert, Handle Pad	1
60	20-2014-7	Battery Retainer	1
240	20-2337-8	Front Case	1
250	20-1328-2	Door Assembly, Right	1
260	20-1328-1	Door Assembly, Left	1
270	20-2105-7	Hinge Pin	4
340	20-2284-7	Seal, Urethane	2
350	20-2121-7	Bezel, Seal Retaining	2
360	40-2069-7	Bracket, Lower Fitment	2
430		Keypad/Overlay, Fractional/Titration	1
	20-3075-7	Keypad/Overlay Assembly, English	
	20-3075-9	Keypad	
	20-3089-7	Overlay, French	
	20-3101-7	Overlay, Italian (Model 1321)	
	20-3095-7	Overlay, Spanish	
	20-3090-7	Overlay, Swedish (Model 1321)	
490	10-3041-7	Guard	1
530		Label, Operating Instructions	1
	20-2356-7	English	
	20-2356-8	French	
	20-2356-9	Italian (Model 1321)	
	20-2356-11	Spanish	
	20-2356-10	Swedish (Model 1321)	
560		Label, Roller Clamp Warning	2
	20-2407-7	English	
	20-2407-8	French	
	20-2407-11	Spanish	
600		Label, Generic Warning	1
	20-2358-7	English	
	20-2358-8	French	
	20-2358-9	Italian (Model 1321)	
	20-2358-11	Spanish	
	20-2358-10	Swedish (Model 1321)	
630	10-2101-7	Label, Battery History	1
640	144095	Label, Battery Replacement	1
680		Label, Air-in-Line	2
	10-2369-7	English	
	10-2133-7	French	
	10-2369-9	Italian (Model 1321)	
	10-2132-7	Spanish	
730	801409	Screw, 4-40x0.43, XREC, SLFTPG	20

Final Assembly, 110V/220V (Continued)

Item	Part Number	Description	Qty.
820	801032	Screw, Machine, 10-32x0.25, XREC PNH	2
830	801326	Screw, Cap, 10-32x0.37, Hex STDHD	4
840	801009	Screw, Machine, 10-32x0.37, XREC PNH	2
860	801042	Screw, Machine, 4-40x0.18, XREC PNH	2
870	809039	Spring, Door	2
930	803215	Washer, Spring Lock, #10	2
1130	834031	Cable Tie, 4", Auto Feed	2
1150	*	Fluid, Medium, Dow 360 – 1000C	AR
1180	303724	Rubber Bumper	4
1190	834042	Seal, 103 Conductive Cord	1
1200	841026	Battery, 6V, 12AH, Lead Acid	1
1210	809095	Bumper-Strip, 1/2 x 1/8 x 1	6
1220	830026	Tape, Clear Vinyl, 0.004 x 1, Single Side Adhesive	2

* Not provided by ALARIS Medical Systems.

Front Case Assembly, 110V/220V

(*Replaces corresponding information in Illustrated Parts Breakdown chapter of maintenance manual.*)

Item	Part Number	Description	Qty.
70	20-1329-1	Door Sensor Assembly	2
80	20-1194-2	Transducer Assembly	2
90		Mechanism Assembly	2
	10-1132-3	Integer	
	10-1132-4	Fractional/Titration	
140	20-1314-1	Air-in-Line/Housing Assembly	2
150		Board Assembly, Power Supply	1
		New Build:	
	142711	(for instrument with Version 2.49 Software)	
	142713	(for instrument with Version 3.44 Software)	
		Reconditioned: (Model 1320)	
	142712	(for instrument with Version 2.49 Software)	
	142063	(for instrument with Version 3.44 Software)	
160		Board Assembly, Display	1
		New Build:	
	20-7040-3	(for instrument with Version 2.49 Software)	
	142331	(for instrument with Version 3.44 Software)	
		Reconditioned: (Model 1320)	
	142059	(for instrument with Version 2.49 Software)	
	142062	(for instrument with Version 3.44 Software)	

Front Case Assembly, 110V/220V (Continued)

Item	Part Number	Description	Qty.
170		Board Assembly, Logic	1
		New Build:	
	20-7039-2	Version 2.49 (Model 1321)	
	142333	Version 3.44 (Model 1320)	
	144706	Version 3.45 replacement (Model 1321)	
	144577	Kit, upgrade to Version 3.45 (Model 1321)	
		(Kit consists of Version 3.45 board assy. and serial number upgrade report form.)	
		Reconditioned: (Model 1320)	
	142058	Version 2.49	
	142061	Version 3.44	
230	20-1338-1	Ground Cable Assembly, Keypad	2
330	10-2094-7	Gasket, Air-in-Line	2
370	20-2303-7	Insulator, Power Supply Board	1
380	143895	Alarm Circuit Assembly, Upper, Mechanism	2
390	10-3046-1	Alarm Circuit Assembly, Lower, Mechanism	2
395	10-1164-1	Top Plate Assembly	2
400	20-2426-7	Mounting Bracket, Hall Sensor	2
410	20-2198-10	Anchor Bracket	2
420	20-2150-7	Roller, Anchor Bracket	2
700	801062	Screw, Machine 6-32x0.38, PNH, SLFLKG	8
710	801063	Screw, Machine 4-40x0.31, PNH, SLFLKG	8
720	801038	Screw, Machine 4-40x0.31, XREC PNH	2
740	801002	Screw, Machine 4-40x0.25, XREC PNH	8
750	801039	Screw, Machine 4-40x0.75, XREC PNH	2
860	801042	Screw, Machine 4-40x0.18, XREC PNH	3
880	809088	Spring, Compression	2
950	803606	Washer, #4 x ¼ x 0.062, Nylon	2
980	803619	Washer, ¼" I.D., ½" O.D., SS	4
990	803002	Washer, Flat, #6	8
1000	803000	Washer, Flat, #4, Zinc-Steel	11
1020	804001	Dowel Pin	2
1030	804201	Cotter Pin	2
1040	20-3043-7	Washer, #4, SS	8
1050	805028	Spacer, Retaining	2
1080	845024	Cable Clamp, Nylon w/adhesive, ¼DX	2
1090	845023	Cable Clamp, Nylon w/adhesive, 1/8DX	2
1130	834031	Cable Tie, 4", Auto Feed	2

Front Case Assembly, 110V/220V (Continued)

Item	Part Number	Description	Qty.
1160	*	Grease, Silicone Molykote 33 MDM	AR
1170	834000	Tie Cord, 0.020-0.080 Diameter	2

* Not provided by ALARIS Medical Systems.

Rear Case Assembly, 110V/220V

(*Replaces corresponding information in Illustrated Parts Breakdown chapter of maintenance manual.*)

Item	Part Number	Description	Qty.
30	980-1015-1	Wrap Assembly, Power Cord	1
100		Transformer/Harness Assembly	1
	142000	(Model 1320)	
	20-1330-2	(Model 1321)	
	20-1330-1	(Titration, BSI)	
110	20-1316-1	Rear Case with Pole Clamp Assembly	1
130	10-1180-1	Audio Switch/Harness Assembly	1
140		Fuse (for AC Receptacle Assembly) (*see figure 1 of this bulletin*)	
	842031	400MA, 250V Slow Blow (Model 1321)	2
	842028	3AG Type, 0.6A, 250V Slow Blow (Model 1320)	1
180	10-2004-7	Spring, A/C Locking	2
190	142325	I/O (Communication) Harness/Board Assembly	1
200		Transistor/Harness Assembly	1
	20-1339-1	(Titration/Fractional)	
	20-1336-1	(Integer)	
210		Audio/Harness Assembly	1
	20-1331-1	(short harness – approximately 4 inches)	
	20-1332-1	(long harness – approximately 15 inches)	
220		AC Receptacle Assembly	1
	20-1333-1	400MA Fuses (2) not included (Model 1321) (*see figure 2 of this bulletin*)	
	20-1335-3	0.6A Fuse (1) included (Model 1320) (*see figure 3 of this bulletin*)	
221	809097	Potential Equalization Earth Ground Stud (Model 1321) (*see figure 4 of this bulletin*)	1
280	10-2150-1	Knob, Pole Clamp	1
290	20-2153-7	Pads, Power Board	2
300	20-2331-7	Gasket, Comm Board Channel A	1
310	20-2332-7	Gasket, Comm Board Channel B	1
320	20-2333-7	Gasket, AC Receptacle	1
470		Power Cord	1
	848012	Australia	
	848008	Continental Europe	
	142758	North America	
	848009	United Kingdom	

Rear Case Assembly, 110V/220V (Continued)

Item	Part Number	Description	Qty.
480	20-2176-7	Retainer, Power cord	1
510		Label Sheet, Rear Case (Model 1320)	1
	143591	Provides the following labels:	
	20-2419-7	Comm Channel A, English	
	20-2418-7	Comm Channel B, English	
	20-2417-7	Comm Channel B, French	
	143515	Fuse Warning, English/French	
	20-2412-7	Hospital Grade Plug Usage, English/French	
	20-2410-8	Nameplate, English/French	
	143592	Provides the following labels:	
	20-2419-11	Comm Channel A, Spanish	
	20-2418-11	Comm Channel B, Spanish	
	143593	Fuse Warning, English/Spanish	
	20-2413-7	Hospital Grade Plug Usage, English/Spanish	
	20-2411-7	Nameplate, English/Spanish	
604		Label, Fuse Warning (*see figure 5 of this bulletin*)	1
	20-2368-7	English (Model 1321)	
	143515	English/French (Model 1320) (also included as part of item 510)	
	143593	English/Spanish (Model 1320) (also included as part of item 510)	
	20-2351-7	French (Model 1321)	
	20-2230-7	Italian (Model 1321)	
	20-2381-7	Spanish (Model 1321)	
	20-2352-7	Swedish (Model 1321)	
606		Label, Nameplate (*see figure 5 of this bulletin*)	1
	142230	English (Model 1321)	
	20-2410-8	English/French (Model 1320) (also included as part of item 510)	
	20-2411-7	English/Spanish (Model 1320) (also included as part of item 510)	
	142231	French (Model 1321)	
	142232	Italian (Model 1321)	
	142234	Spanish (Model 1321)	
	142233	Swedish (Model 1321)	
641	20-2246-7	Label, Ground (Model 1321) (*see figure 6 of this bulletin*)	1
666		Label, Com Channel A (*see figure 5 of this bulletin*)	1
	20-2298-7	English (Model 1321)	
	20-2419-7	English (Model 1320) (also included as part of item 510)	
	20-2345-7	French	
	20-2419-9	Italian (Model 1321)	
	20-2419-11	Spanish (Model 1320) (also included as part of item 510)	
	20-2379-7	Spanish (Model 1321)	
	20-2346-7	Swedish (Model 1321)	

Rear Case Assembly, 110V/220V (Continued)

Item	Part Number	Description	Qty.
667		Label, Comm Channel B (*see figure 5 of this bulletin*)	1
	20-2289-14	English (Model 1321)	
	20-2418-7	English (Model 1320) (also included as part of item 510)	
	20-2417-7	French (Model 1320) (also included as part of item 510)	
	20-2347-7	French (Model 1321)	
	20-2418-9	Italian (Model 1321)	
	20-2418-11	Spanish (Model 1320) (also included as part of item 510)	
	20-2380-7	Spanish (Model 1321)	
	20-2348-7	Swedish (Model 1321)	
668	20-2406-7	Label, Homologation, French (Model 1321) (*see figure 5 of this bulletin*)	1
669		Label, Hospital Grade Plug Usage (Model 1320) (*see figure 5 of this bulletin*)	1
	20-2412-7	English/French (also included as part of item 510)	
	20-2413-7	English/Spanish (also included as part of item 510)	
690	143896	Label, Pole Clamp	1
740	801002	Screw, Machine 4-40x0.25, XREC PNH	1
760	801324	Screw, Cap, 10-32x1.75, Hex STDHD	2
770	801019	Screw, Machine, 5/16-18x0.50, SLTD PNH	1
790	801004	Screw, Machine, 4-40x0.50, XREC PNH	2
800	801032	Screw, Machine, 10-32x0.25, XREC PNH	1
810	801000	Screw, Machine, 6-32x0.25, XREC PNH	2
850	801116	Screw, Machine, 6-32x0.37, XREC FLH	1
890	803210	Washer, Lock, 5/16	1
900	803215	Washer, Spring Lock, #10	2
910	803216	Washer, Internal Lock, 3/8	1
920	803204	Washer, Internal Lock, 010	1
940	803612	Washer, Shoulder, #4, Nylon	1
941	803217	Washer, 6.4MM, SHPRF (Model 1321) (*see figure 4 of this bulletin*)	1
942	803032	Washer, #6, Flat (Model 1321) (*see figure 4 of this bulletin*)	1
943	802012	Nut, M-6, Hex (Model 1321) (*see figure 4 of this bulletin*)	1
960	803021	Washer, #6, SS	2
1060	802612	Nut, 3/16, SLFTHD	4
1070	809061	Snap, Eyelet Stud	1
1075	802007	Nut, 3/8-32, Dress	1
1100	845005	Cable Clamp, 1/8 x 21/64, Nylon	1
1105	809029	Cable Clamp, 3/16	1
1130	834031	Cable Tie, 4", Auto Feed	1
1140	*	Sealant Adhesive, RTV 162	AR
1230	847034	Heatsink Insulator, Power Semicond to-226	1

* Not provided by ALARIS Medical Systems.

Figure 1 - Fuse Location in AC Receptacle Assembly

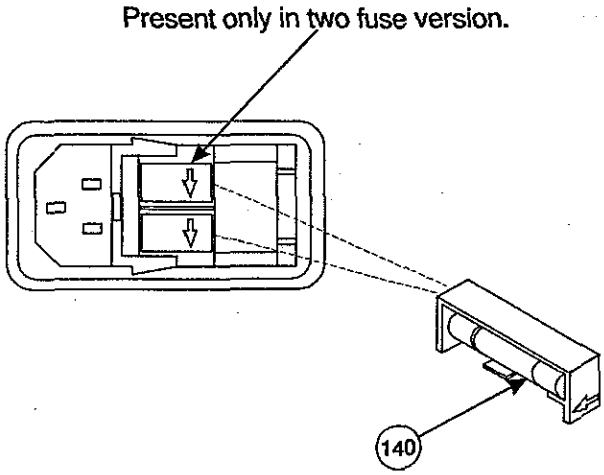


Figure 2 - AC Receptacle Assembly Wiring – Two Fuse Version (Model 1321)

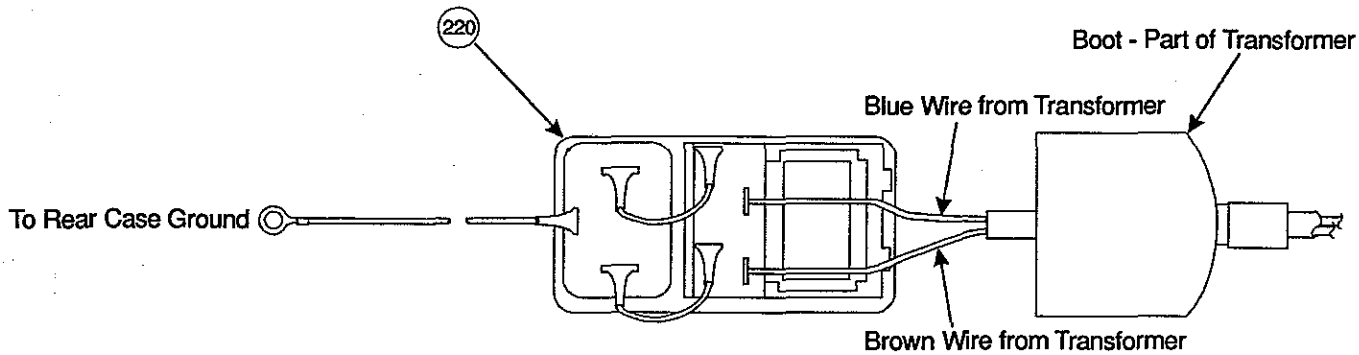


Figure 3 - AC Receptacle Assembly Wiring – One Fuse Version (Model 1320)

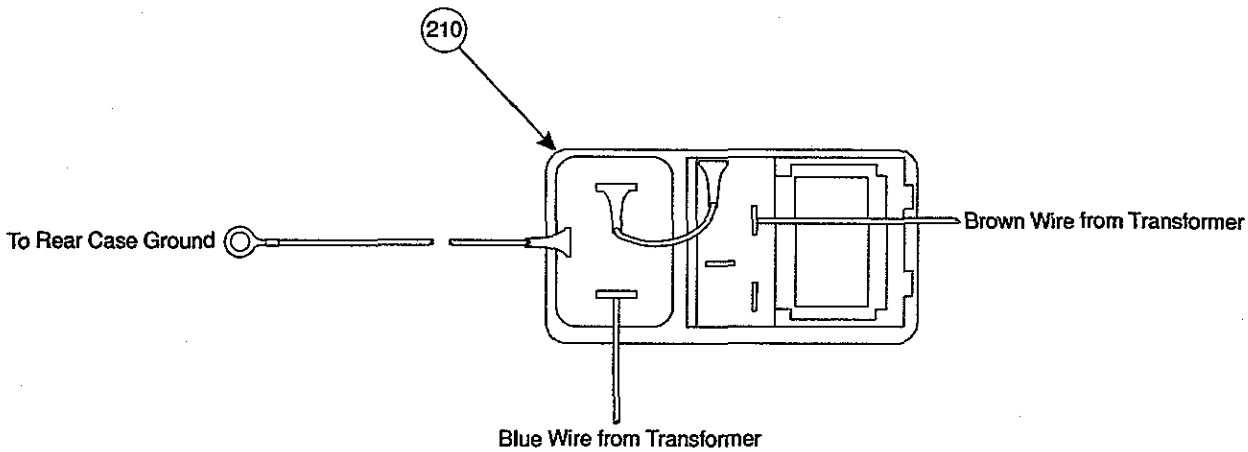


Figure 4 - Earth Ground Stud Attachment to Rear Case (Model 1321)

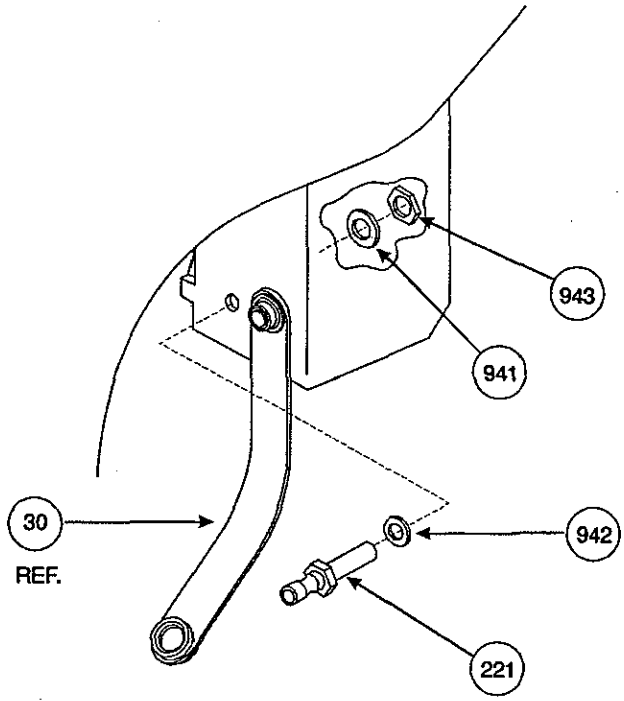


Figure 5 - Rear Case Label Locations

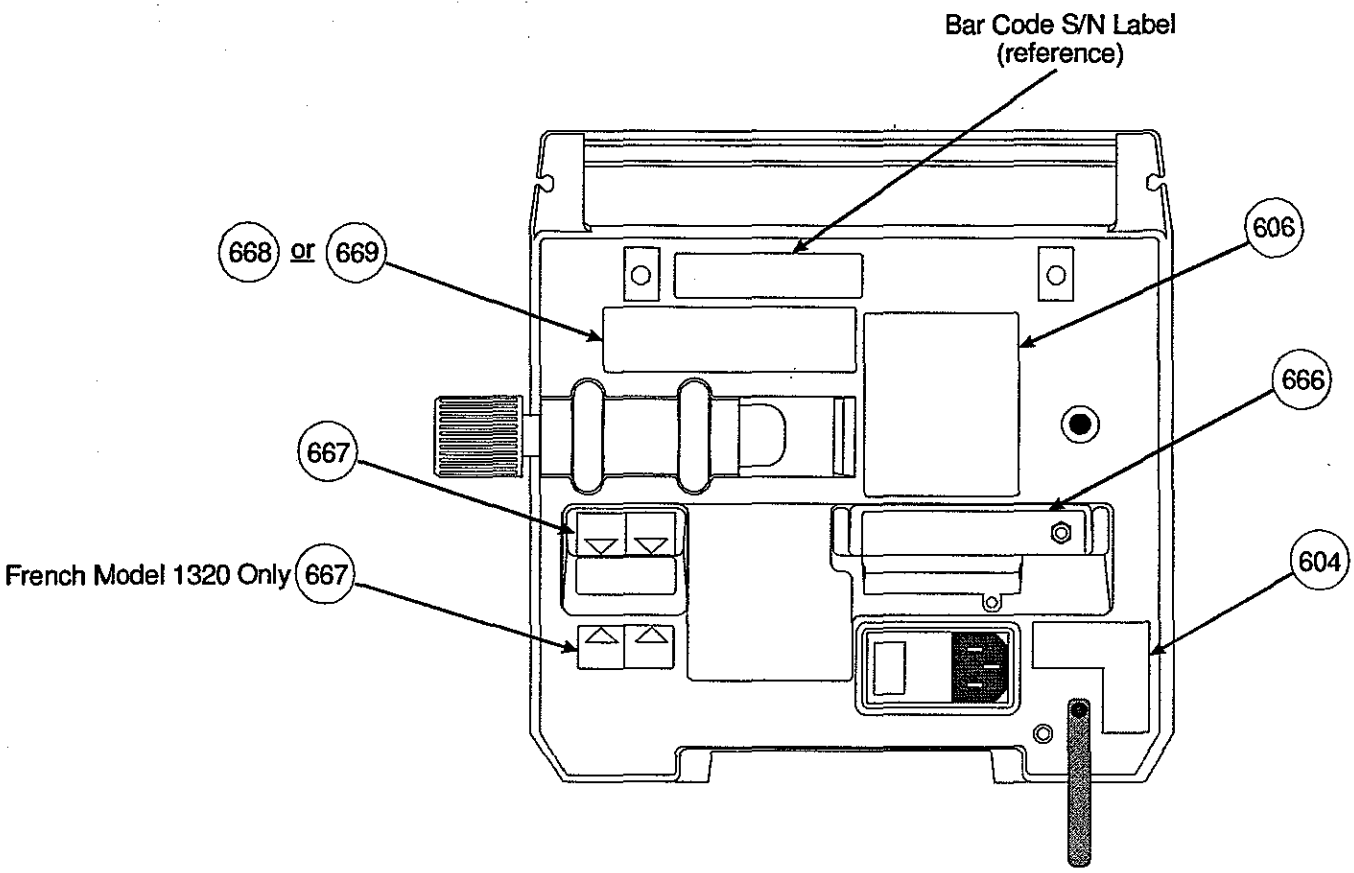
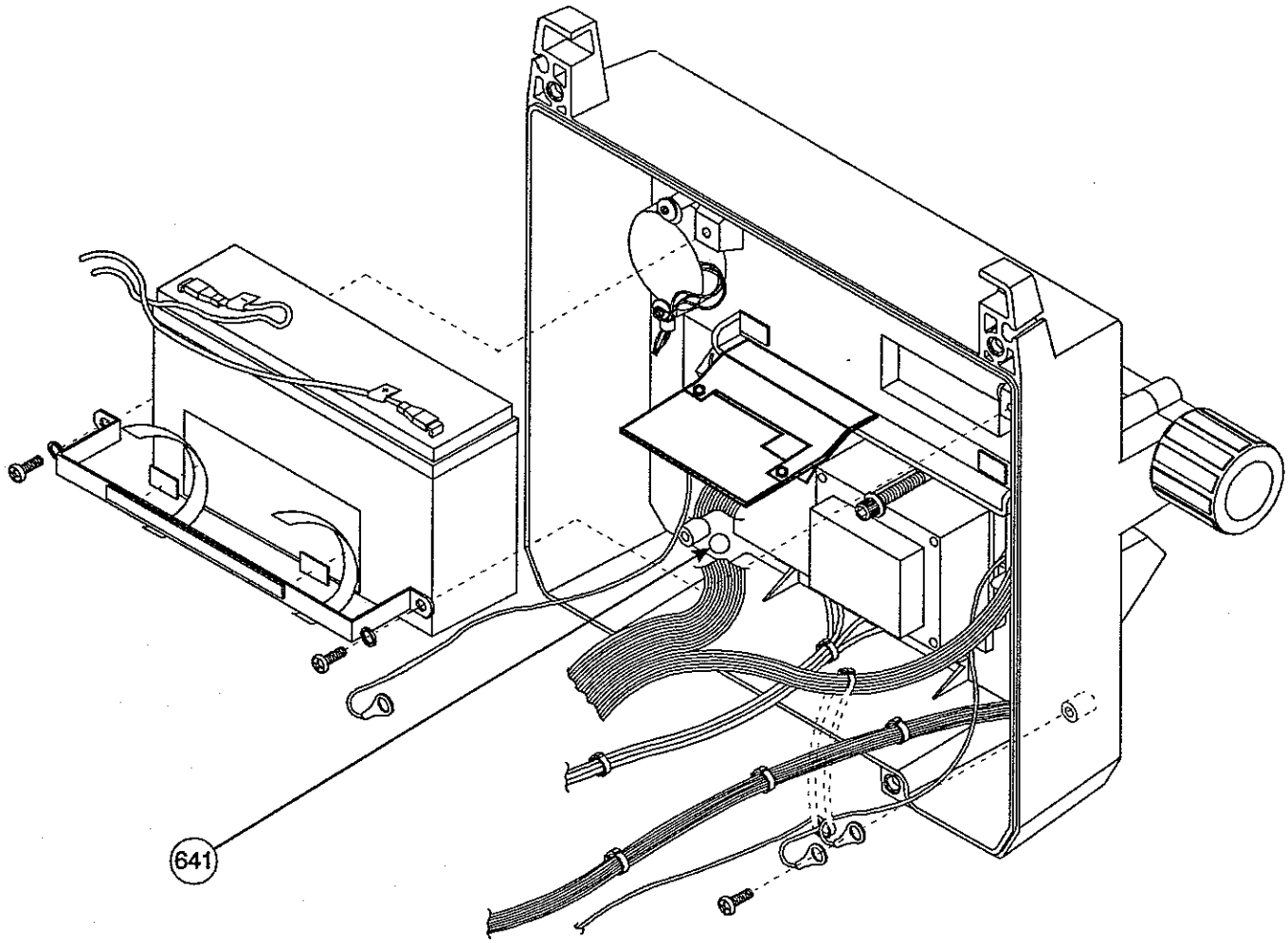


Figure 6 - Ground Label Location (Model 1321)



Display Board Assembly, 110V/220V

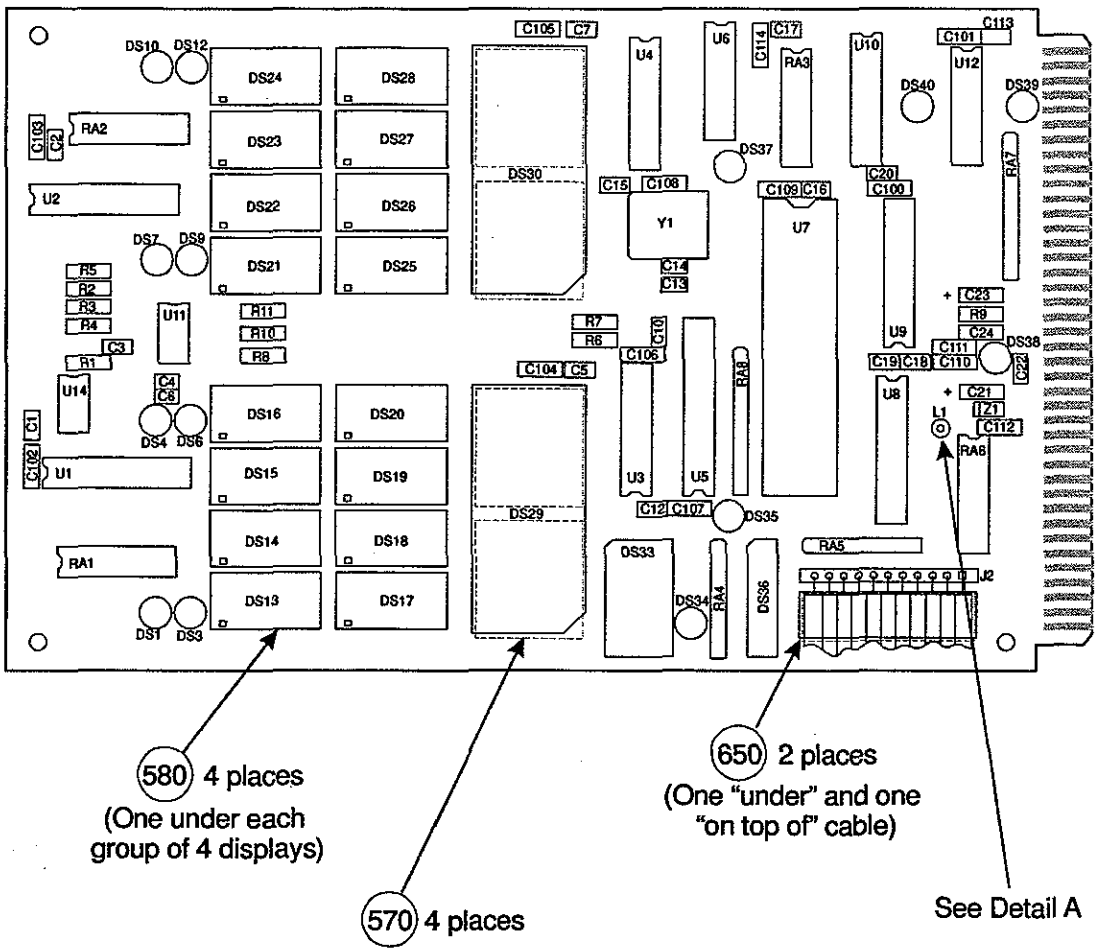
(*Supplement to Illustrated Parts Breakdown chapter of maintenance manual.*)

Ref Des	Part Number	Description	Qty.
	142331	Board Assembly, Display (*see figures 7 and 8 of this bulletin*)	1
		Capacitors	
C1 - C3, C5, C7, C10, C12, C15 - C20, C22, C113	811247-104	Ceramic,0.1µF, 50V, 20%, Z5U RAD	15
C4, C6	811245-300A	Ceramic, 30pF, 50V, 5%, NPO AXL	2
C13, C14	811247-150A	Ceramic, 15pF, 50V, 20%, NPO AXL	2
C21, C22	811116-685A	Tantalum, 6.8µF, 10V, 10%, AXL	2
C24	811247-224A	Ceramic, 0.22µF, 50V, 20%, Z5U AXL	1
C100-C112, C114	811946-102	Ceramic, 1000pF, 50V, 10%, NPO RAD	14
		Diode	
Z1	813067	VA1000, TVS, 15V, 0.4J, AXL	1
		Displays	
DS1, DS4, DS7, DS10, DS34, DS35, DS37-DS40	813305	LED, Green	10
DS3, DS6, DS9, DS12	813400	LED, Red	4
DS13-DS28	815040	7 Segment, Green	16
DS29, DS30	815057	8 Character, Yellow	2
DS33	815041	LED, Green, Light Bar, 16 Pin	1
DS36	815038	LED, Green, Light Bar, 6 Pin	1
		Integrated Circuits	
U1, U2	812140	DP8313, Octal Latch, 20 Pin	2
U3, U4	812119	UDN2595A, Current-Sink Driver, 18 Pin	2
U5	812161	74HC154, Decoder/Demux, 24 Pin	1
U6, U12	812156	74HC4051, Multiplexer/Demux, 16 Pin	2
U7	20-1092-1	8742A, Peripheral Interface, 40 Pin	1
U8	812139	74HC573, Octal Latch, 20 Pin	1
U9	812117	74C923, 20-Key, 20 Pin	1
U10	812118	UDN2585A, Source Driver, 20 Pin	1
U11	812219	TLC27M2A, OP AMP 2, 8 Pin	1

Display Board Assembly, 110V/220V (Continued)

Ref Des	Part Number	Description	Qty.
		Integrated Circuits (Continued)	
U14	812218	LM393, Volt COMPTR 5, 8 Pin	1
		Resistors	
R1	810125-472	4.7KΩ, ¼W, 5%, AXL	1
R2	810229-6042	60.4KΩ, ¼W, 1%, Metal Film	1
R3	810221-4022	40.2KΩ, ¼W, 1%, Metal Film	1
R4	810229-203	20KΩ, ¼W, 1%, Metal Film	1
R5, R8, R10, R11	810221-1003	100KΩ, ¼W, 0.1%, Metal Film	4
R6, R7, R9	810125-103	10KΩ, ¼W, 5%, AXL	3
		Resistor Networks	
RA1, RA2	812172	220Ω, 2%, 16 Pin	2
RA3	812102	82Ω, 2%, 16 Pin	1
RA4, RA5	810900-271H	270Ω, 2%, , 0.2W, 8 Pin	2
RA6	812153	10KΩ, 2%, 16 Pin	1
RA7	810900-473	47KΩ, 0.2W, 2%, 10 Pin	1
RA8	810900-223	2.2KΩ, , 0.2W, 2%, 10 Pin	
		Miscellaneous	
J2	20-3077-1	Keypad Interface Cable	1
L1	815125	Inductor, Ferrite Bead	1
Y1	815020	Crystal, HC49U, 20pF, 6MHz	1
(item 570)	805036	Spacer, .6STDF, 16 Pin	4
(item 580)	20-3066-7	Spacer, One Piece, Display	4
(item 650)	830000	Tape, Mylar	AR

Figure 7 - Display Board Assembly, 1320/1321



DETAIL A
(Clad side of board)

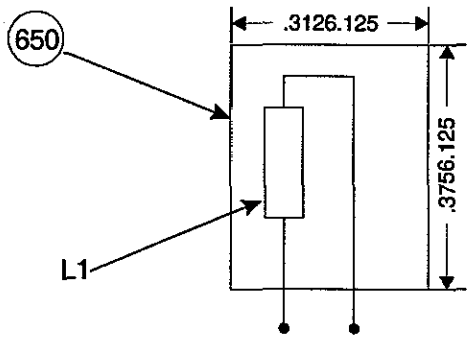


Figure 8 – Display Board Schematic, 1320/1321

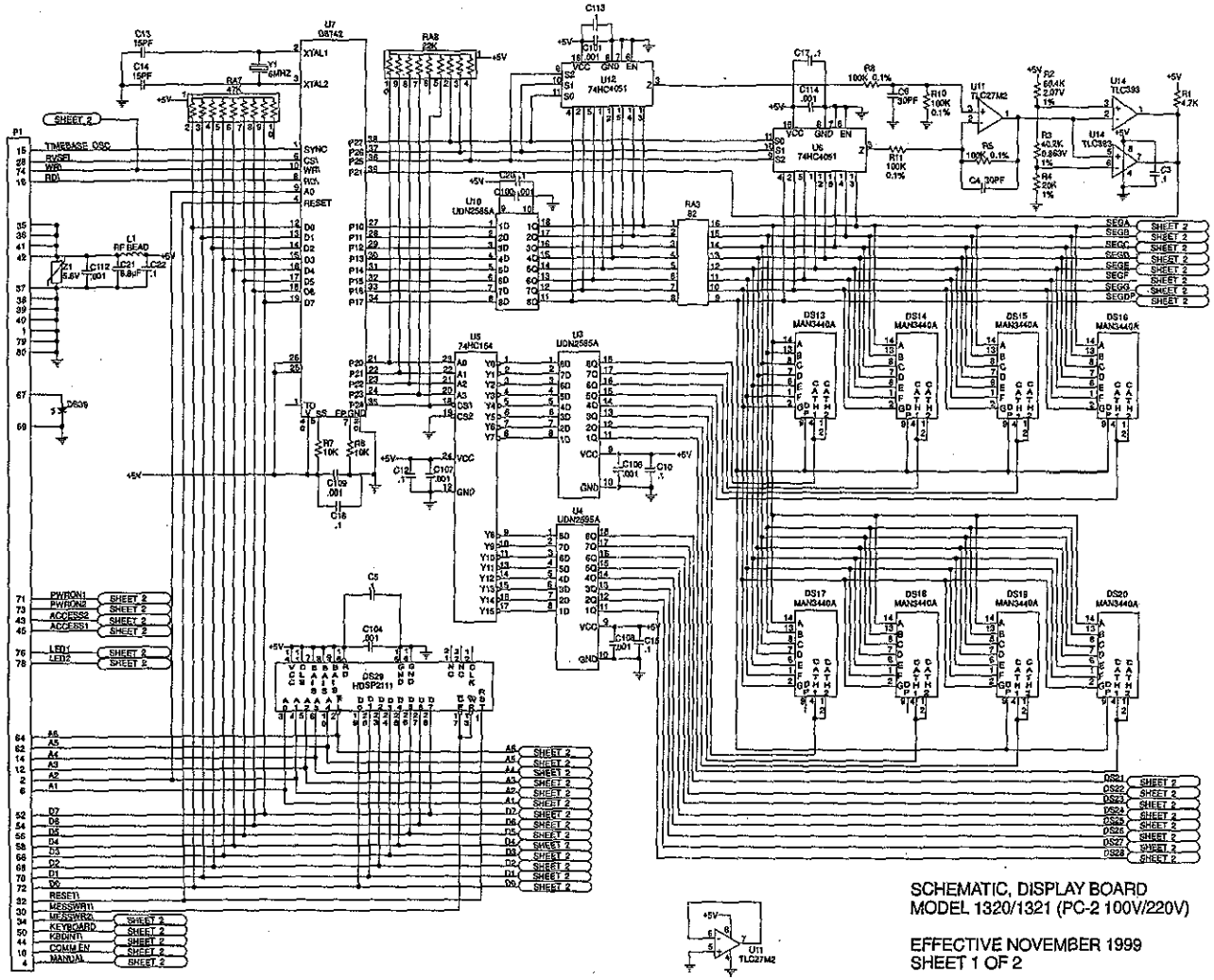
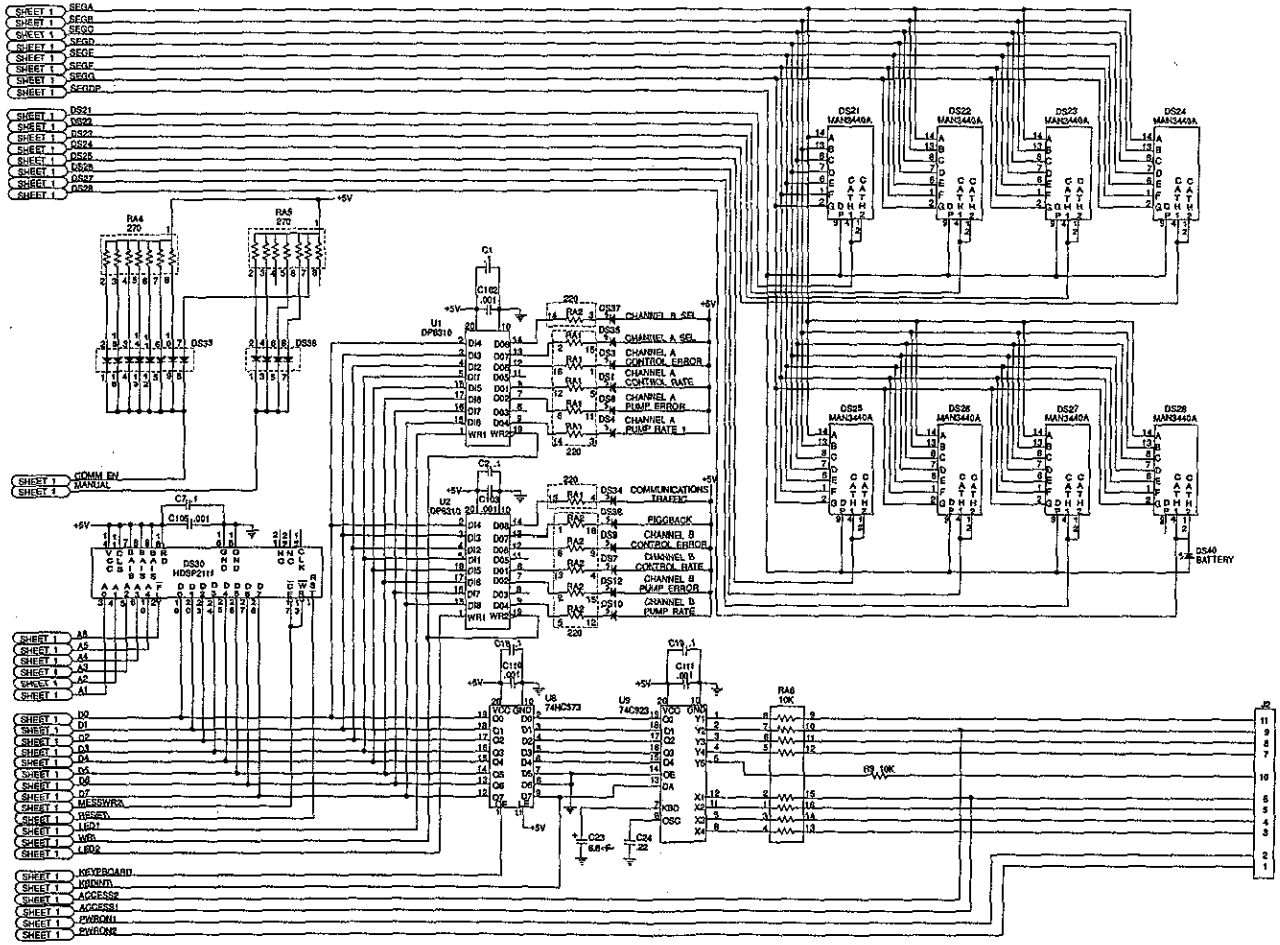


Figure 8 – Display Board Schematic, 1320/1321 (Continued)



SCHEMATIC, DISPLAY BOARD
MODEL 1320/1321 (PC-2 100V/220V)

EFFECTIVE NOVEMBER 1999
SHEET 2 OF 2